**DEPARTMENT OF DEFENSE**

**GENERAL SERVICES ADMINISTRATION**

**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

**48 CFR Part 31**

**Federal Acquisition Regulation (FAR); Reasonableness of Contract Costs**

**AGENCIES:** Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Proposed rule.

**SUMMARY:** The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering changes to Federal Acqusition Regulation (FAR) 31.201–3, Determining reasonableness.

**COMMENTS:** Comments should be submitted to the FAR Secretariat at the address shown below on or before May 2, 1986, to be considered in the formulation of a final rule.

**ADDRESS:** Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets NW., Room 4041, Washington, DC 20405.

Please cite FAR Case 86–11 in all correspondence related to this issue.

**FOR FURTHER INFORMATION CONTACT:** Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523–4755.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

The change to FAR 31.201–3 under consideration is designed to shift the burden of proof on the issue of reasonableness of contract costs from the Government to the contractor, abolish the presumption of reasonableness which attaches to incurred costs, and simplify the list of considerations that impact reasonableness determinations. This proposed rule is considered necessary to ensure that only reasonable costs are paid under Government contracts. Moreover, the proposed coverage is based, in part, upon section 933 of the Defense Procurement Improvement Act of 1985 (Pub. L. 99–145).

**B. Regulatory Flexibility Act**

The proposed change to FAR 31.201–3 is not expected to have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et. seq.) because the proposed coverage is designed primarily to clarify the term "reasonable cost" and to shift the burden of proof for establishing reasonableness of costs to the contractor when a cost is challenged by the contracting officer. A prudent business should already be maintaining adequate documentation to satisfy this burden of proof.

**C. Paperwork Reduction Act**

The Paperwork Reduction Act (Pub. L. 96–511) does not apply because the proposed change to FAR 31.201–3 does not impose any additional reporting or recordkeeping requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501 et. seq.

**List of Subjects in 48 CFR Part 31**

Government procurement.

Dated: February 24, 1986.

**Lawrence J. Rizzi,**

*Director, Office of Federal Acquisition and Regulatory Policy.*

Therefore, it is proposed that 48 CFR Part 31 be amended as follows:

**PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES**

1. The authority citation for Part 31 continues to read as follows:

**Authority:** 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

2. Section 31.201–3 is revised to read as follows:

**31.201–3 Determining reasonableness.**

(a) A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person in the conduct of competitive business. Reasonableness of specific costs must be examined with particular care in connection with firms or their separate divisions that may not be subject to effective competitive restraints. No presumption of reasonableness shall be attached to the incurrence of costs by a contractor, and upon challenge of a specific cost by the contracting officer, the burden of proof shall be upon the contractor to establish that such cost is reasonable.

(b) What is reasonable depends upon a variety of considerations and circumstances, including—

(1) Whether it is the type of cost generally recognized as ordinary and necessary for the conduct of the contractor's business or the contract performance;

(2) Generally accepted sound business practices, arm's-length bargaining, and Federal and State laws and regulations;

(3) The contractor's responsibilities to the Government, other customers, the owners of the business, employees, and the public at large; and

(4) Any significant deviations from the contractor's established practices.

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Part IV

# Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 207, 210, 225, 226, 510, 514, and 558

New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Re Medicated Feed Applications; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 207, 210, 225, 226, 510, 514, and 558**

**[Docket No. 77N-0076]**

# New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Re Medicated Feed Applications

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule revising the current procedures and requirements concerning conditions of approval for the manufacture of animal feeds containing new animal drugs. This final rule is based on the tentative final rule published in the **Federal Register** of July 29, 1983 (48 FR 34574) and amended in the **Federal Register** of November 1, 1983 (48 FR 50358).

**EFFECTIVE DATES:** These regulations shall become effective May 2, 1986, except that the provisions of 21 CFR 558.4(d), Category II, requiring the submission and approval of medicated feed applications for products formerly exempt from such requirement shall become effective March 3, 1987.

**FOR FURTHER INFORMATION CONTACT:** George Graber, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.

**SUPPLEMENTARY INFORMATION:**

## I. Background

This final rule implements the conclusions of the Medicated Feed Task Force of 1978 that were announced in the **Federal Register** of December 15, 1978 (48 FR 58634). The Task Force concluded that the existing program is the result of piecemeal policies affecting animal drugs resulting from application of the Federal Food, Drug, and Cosmetic Act (the act) enacted in 1938, as it evolved before and after the passage of the Animal Drug Amendments of 1968 (the amendments) (Pub. L. 90-399). Even after passage of the amendments, the medicated feed program continued to grow in a haphazard way. Exemptions from section 512(m) of the act (21 U.S.C. 360b(m)) resulted in feeds containing some carcinogenic drugs being exempt from the requirement for an approved medicated feed application, whereas feeds containing some drugs with wide margins of safety were subject to only partial or no exemptions. This anomalous situation was compounded by inconsistencies in the exemptions among drugs and among uses of individual drugs. For example, a new animal drug in feed may be exempted for one species but not others, making the regulatory program confusing and difficult to enforce because drugs marketed under the exempted use may be diverted to a nonexempted use.

The Task Force concluded that the current medicated feed program lacks uniformity. It recommended, among other things, that regulatory control of feeds containing new animal drugs that pose a potential risk to human beings from residues be strengthened, and that control of feeds containing drugs that pose little risk to human beings be reduced, thereby better utilizing the limited resources of the agency. Requirements for approved medicated feed applications should be based upon the degree of risk from use of the drug, either in terms of the toxicity of the drug itself or the concentration of the drug.

In the **Federal Register** of January 8, 1981 (46 FR 2456), FDA addressed the comments received on the Task Force report and proposed regulations based on the Task Force's recommendations. Approximately 570 comments were received on the proposal. The comments were from the animal drug industry, commercial feed manufacturers, on-farm mixers (mixer-feeders), veterinary practitioners, and Federal and State agencies. Following an evaluation of these comments, the agency concluded that additional changes should be made in the regulations to further simplify them without compromising the central focus of the Task Force. The agency concluded that the drugs used in animal feeds should be placed into categories based on their likelihood of producing unsafe residues in the edible products of treated animals. The agency's responses to the comments were discussed in detail in the tentative final rule published in the **Federal Register** of July 29, 1983 (48 FR 34574).

In the tentative final rule, the agency made two significant changes from the 1981 proposal. First, the agency reduced the number of drug categories from three to two. Second, the agency decided to exempt from the requirement of an approved medicated feed application the manufacture of Type B and Type C medicated feeds from Type A medicated articles listed in Category I. Those medicated feed manufacturers using solely Type A medicated articles in Category I would not need to register under section 510(b) of the act (21 U.S.C. 360(b)). The agency also made a number of minor editorial and technical revisions.

## II. Provisions of This Final Rule

### *A. Drug Categories*

The two drug categories defined in the July 29, 1983 tentative final rule are retained.

Category I consists of those drugs for which no withdrawal period is required at the lowest use level for each species for which they are approved. Drugs in this category include: aklomide, ammonium chloride, amprolium with ethopabate, bacitracin (from bacitracin methylene disalicylate or zinc bacitracin), bambermycins, buquinolate, chlortetracyline, coumaphos, decoquinate, dichlorvos, erythromycin (thiocyanate salt), fenbendazole, iodinated casein, monensin, nequinate, niclosamide, nystatin, oleandomycin, oxytetracycline, penicillin, penicillin with streptomycin, poloxalene, salinomycin, tylosin, virginiamycin, and zoalene.

Category II consists of those drugs: (1) For which a withdrawal period is required at the lowest use level for at least one species for which they are approved; or (2) that are regulated on a "no-residue" basis or with a "zero" tolerance because of a carcinogenic concern, regardless of whether a withdrawal period is required.

Drugs in this category include: Amprolium, arsanilate sodium, arsanilic acid, butynorate, carbadox, carbarsone, clopidol, dimetridazole, famphur, furazolidone, halofuginone hydrobromide, hygromycin B, ipronidazole, lasalocid, levamisole, lincomycin, melengestrol acetate, morantel tartrate, neomycin, nicarbazin, nitarsone, nitrofurazone, nitromide-sulfanitran, novobiocin, phenothiazine, piperazine, pyrantel tartrate, robenidine, ronnel, roxarsone, sulfadimethoxine-ormetoprim, sulfaethoxypyridazine, sulfamerazine, sulfamethazine, sulfanitran with aklomide, sulfaquinoxaline, sulfathiazole, and thiabendazole.

### *B. Definitions*

As stated in the 1983 tentative final rule, the definitions clearly distinguish between those medicated feed articles that constitute new animal drugs subject to approval under section 512(c) of the act, and animal feeds containing new animal drugs subject to approval under section 512(m)(2) of the act. The definitions also distinguish between the kinds of medicated feeds subject to approval under section 512(m) of the act. Type A medicated articles will be regulated as new animal drugs. Type B and Type C medicated feeds will be

regulated as animal feeds containing new animal drugs.

*Type A medicated article.* The definition in the 1983 tentative final rule is retained without change. A Type A medicated article is a standardized product intended for use in the manufacture of a medicated animal feed. It is limited to use solely in accordance with its published regulation and contains one or more new animal drugs for use in the manufacture of a medicated animal feed. It is produced from a drug component or another Type A medicated article, and is subject to the requirements for approval under section 512(b) of the act. It usually includes a diluent (carrier substance), and must be further mixed to produce either another Type A medicated article, or a Type B or Type C medicated feed.

*Type B medicated feed.* The definition in the 1983 tentative final rule is retained without change. A Type B medicated feed is an animal feed containing a new animal drug and that is intended solely for manufacture into another Type B or a Type C medicated feed. It is produced from a drug component, a Type A medicated article, or another Type B medicated feed. If it is produced from a drug component, it must be the subject of an application approved under section 512(c) of the act. If it is produced from a Category II, Type A article, it must be the subject of an approval under section 512(m) of the act. A Type B medicated feed conforms to the definition of animal feed in section 201(x) of the act (21 U.S.C. 321(x)). Before being fed to animals, however, it has to be substantially diluted with one or more nutrients to produce a Type C medicated feed.

For the purpose of defining the dividing line between a Type A medicated article and a Type B medicated feed, the criteria of the tentative final rule are retained. Thus, the maximum permitted concentration of drug in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs, and 100 times the highest continuous use level for Category II drugs. At approved levels above those concentrations, the product is a Type A medicated article. The "highest continuous use level" means the highest dosage at which a drug is approved for continuous use (14 days or more) or, if a drug is not approved for continuous use, the highest level used for disease prevention or control. If a drug is approved for multiple species at different use levels, the highest level would govern under this definition.

*Type C medicated feed.* In response to comments, FDA has revised the definition of the tentative final rule to conform to the preamble of the tentative final rule. A Type C medicated feed is a medicated animal feed containing a new animal drug that may be offered as a complete feed, or when permitted under Subchapter E of Title 21 of the Code of Federal Regulations, it may be fed top dressed or offered free-choice in conjunction with other animal feed to supplement the animals' total daily ration. It is produced by substantially diluting a drug component, Type A medicated article, or Type B or Type C medicated feed with feed ingredients to a level of use that is covered by an approved new animal drug application (NADA). If produced from a drug component, it must be the subject of an application approval under section 512(c) of the act. If produced from a Category II, Type A medicated article, it must be the subject of an approval under section 512(m) of the act.

Type A medicated articles and Type B and Type C medicated feeds have different requirements for approval, manufacture, and registration. These requirements are described in the following sections.

### *C. New Animal Drug Applications*

All Type A medicated articles are new animal drugs. Their manufacture requires an approved NADA under section 512(c) of the act and § 514.105(a) of the regulations (21 CFR 514.105(a)). Also, the manufacture of Type B or Type C medicated feeds from a drug component requires an approved NADA under section 512(c) of the act. This final rule does not change those existing requirements.

### *D. Medicated Feed Applications*

No changes in the 1983 tentative final rule were made. Therefore, the submission of a medicated feed application for the manufacture of a Type B or Type C medicated feed from a Type A medicated article will not be required for Category I drugs. A medicated feed application also will not be required for the manufacture of a Type B or Type C medicated feed from a Type B, Category I medicated feed.

For Category II drugs, the final rule waives the requirements of section 512(m) of the act for submission of a medicated feed application for the manufacture of a Type B or Type C medicated feed using a Type B medicated feed. The use of a Category II, Type A medicated article in manufacturing a Type B or Type C medicated feed must be the subject of an approved medicated feed application.

### *E. Current Good Manufacturing Practice (CGMP)*

The manufacture of a Type A medicated article is subject to the existing CGMP regulations in Part 226 [21 CFR Part 226] covering the manufacture of medicated premixes. The manufacture of a Category II, Type B or Type C medicated feed from a Type A medicated article will be subject to existing §§ 225.1 through 225.115 (21 CFR 225.1 through 225.115). These sections provide CGMP requirements for the production of medicated feeds from Type A medicated articles when an approved medicated feed application is required. New §§ 225.120 through 225.202 provide CGMP regulations for the manufacture of medicated feeds for which the requirements of section 512(m) of the act have been waived.

### *F. Registration*

Under the authority of section 510(g)(4) of the act, the agency will exempt from registration under section 510(b) of the act those firms manufacturing medicated feeds for which the requirements for submission and approval of medicated feed applications have been waived. Thus, registration will be required only for all firms manufacturing medicated feeds from Category II, Type A articles.

### *G. Summary of Requirements*

The following table summarizes the major provisions of this final rule and related requirements:

CATEGORY I DRUGS

| Starting drug product | Medicated product manufactured | FDA form | FDA registration | Good manufacturing practice regulations (Title 21) | Biennial GMP inspections |
|---|---|---|---|---|---|
| Drug component | Type A, B, or C | 356 (new animal drug application). | Yes | Part 226 | Yes. |
| Type A | Type A | 356 (new animal drug application. | Yes | Part 226 | Yes. |
| Type A | Type B or C | None | No | §§ 225.120-225.202 | No. |
| Type B | Type B or C | None | No | §§ 225.120-225.202 | No. |

CATEGORY II DRUGS

| Starting drug product | Medicated product manufactured | FDA form | FDA registration | Good manufacturing practice regulations (Title 21) | Biennial GMP inspections |
|---|---|---|---|---|---|
| Drug component | Type A, B, or C | 356 (new animal drug application). | Yes | Part 226 | Yes. |
| Type A | Type A | 356 (new animal drug application). | Yes | Part 226 | Yes. |
| Type A | Type B or C | 1900 (medicated feed application). | Yes | §§ 225.10–225.115 | Yes. |
| Type B | Type B or C | None | No | §§ 225.120–225.202 | No. |

**III. Comments on the July 29, 1983 Tentative Final Rule**

Approximately 93 comments on the tentative final rule were received. A number of the comments addressed the same issues as those submitted in response to the 1981 proposal; FDA responded to those comments in depth in the preamble of the tentative final rule. Those responses, which continue to reflect the position of the agency and which will not be repeated here, relate to the following:

1. Authority to revoke waivers from section 512(m) of the act through rulemaking (48 FR 34577).

2. Regulation of medicated feeds based upon intended use, or species for which the medicated feed is labeled, rather than on drug concentration (48 FR 34577).

3. Basing an exemption on no withdrawal period at the lowest continuous use level (48 FR 34578).

4. Including reference to the Association of American Feed Control Officials' (AAFCO) "Official Publication" as an official source for defining nutrient ingredients (48 FR 34578).

5. Including a drug component ("bulk drug") in the definition of a "Type A medicated article" (48 FR 34578).

6. Permitting the use of any approved source of a Type A medicated article in a medicated feed application (48 FR 34579).

7. Elimination of medicated feed applications as obsolete and duplicative, on the basis that registration and conformity with current good manufacturing practices should be adequate for regulatory purposes (48 FR 34577).

8. "New drug" status of products in § 558.20 (21 CFR 558.20) (48 FR 34580).

*A. Criteria for Exemption From Section 512(m) of the Act*

1. Numerous comments requested that the agency not exempt Category I, Type A medicated articles. The comments stated that requiring medicated feed applications for the use of all Type A articles, both Category I and Category II, would provide a realistic scheme of control.

The basis for reducing the regulatory requirements was discussed in the preamble to the tentative final rule. The agency stated that it believes that it is highly unlikely that the use of these drugs in feed would result in unsafe drug residues in the edible products of food-producing animals. Because the agency wants to concentrate its efforts in the area of potential unsafe residues in food derived from treated animals, it is essential that the regulatory burden be reduced in areas where such potential is minimal.

2. A number of comments stated that it would be inequitable to require an NADA for the manufacture of a Type A medicated article from a Type A medicated article for Category I drugs in view of the fact that manufacture of a Type B or Type C medicated feed requires no approved application for use of a Type A medicated article.

A Type A medicated article is itself a new animal drug as defined in section 201(w) of the act and as such is required to be the subject of an approved application submitted under section 512(b) of the act. Because such articles contain high concentrations of new animal drugs, their manufacture should be subject to premarketing clearance.

Alternatively, the comments requested that the maximum drug level of Category I, Type B medicated feed be increased from 200 to 400 times the highest continuous use level and that the use of Category I, Type A medicated articles require an approved medicated feed application.

The agency has considered the request that the maximum level of a Type B medicated feed be raised to 400 times and found that to do so would in a number of instances cause the maximum level of the drug in Type B medicated feed to exceed the levels provided for in the approved NADA for a Type A medicated article. Under these circumstances, it would be illogical to increase the maximum level permitted in a Type B medicated feed.

3. A number of comments requested that the current waivers from the requirement of a medicated feed application be retained and that the current waiver criteria be incorporated into the category definitions.

The agency does not agree. The inconsistencies in the current program have resulted in part from the use of outdated waiver provisions. The agency has considered the existing waiver criteria in developing this final rule.

4. Seven comments requested that exemption granted under § 558.15 be retained under the new program.

The tentative final rule published July 29, 1983, inadvertently failed to include the exemption proviso in § 558.15(g). A correction document published on November 1, 1983 (48 FR 50358) reinserted the proviso. As corrected, § 558.15 is essentially unchanged and the exemption continues as before.

5. Four comments suggested that the proposed amendment to § 207.10(f) (21 CFR 207.10(f)) be reworded to conform with the exemption criteria.

The agency agrees and has made the requested change.

6. Two comments stated that there should be no exemption from the requirement of an approved medicated feed application for use of Category II, Type B medicated feeds.

The agency continues to believe that the Category II, Type B medicated feeds should be exempted from the requirement of an approved medicated feed application. As discussed in the preamble to the tentative final rule (48 FR 34577), the agency believes that "[t]he more concentrated the source of the drug, the greater would be the impact of error in manufacturing." The agency previously concluded that the likelihood of producing unsafe residues from mixing errors when a Category II, Type B medicated feed is used is low enough to justify the exemption. The comments presented no new information to cause the agency to reverse its previous decision.

7. Two comments questioned the rationale for placing penicillin and tetracycline in Category I considering the agency's announced concern about their use in feed at subtherapeutic levels.

Penicillin and the tetracyclines are placed in Category I because of the unlikelihood of their use in animal feeds causing unsafe drug residues in edible products of animal origin. As discussed above, the agency believes that drugs with a greater potential for causing unsafe drug residues in human food (Category II) should be subject to more stringent regulatory and manufacturing controls than drugs with less potential

for causing unsafe residues in human food (Category I).

In comparison, the agency's concern with the use of penicillin and the subtherapeutic use of the tetracyclines in animal feeds is unrelated to the potential of a drug to result in unsafe drug residues in human food from its use in medicated feeds. In 1977, FDA proposed to prohibit the use of penicillin in animal feeds and to restrict the subtherapeutic animal feed use of the tetracyclines. FDA proposed to take that action because it believed that, among other things, the continued feeding of penicillin and the tetracyclines to animal results in an increase of bacterial strains that are resistant to one or more antimicrobial drugs, and that these antibiotic-resistant organisms may be transferred to humans or the antibiotic resistance will be transferred to another organism that causes disease. The end result is a situation where the antibiotic resistance interferes with the treatment of infectious diseases. Accordingly, the possible development of drug-resistant bacteria is a totally separate issue that is procedurally unrelated to this final rule.

Subsequently, congressional committee reports stated that FDA should hold the matter in abeyance pending the final results from ongoing studies. These studies, to assess further whether these uses of penicillin and the tetracyclines have a potentially significant impact on human health, have now been completed and the agency is currently reviewing the findings. A recently published study by the Centers for Disease Control in *The New England Journal of Medicine*, September 6, 1984, Vol. 311, pp. 617–622, reported that antimicrobial-resistant organisms of animal origin can cause serious human illness. FDA is considering the results of that study, along with other information, in deciding what action to take with respect to these uses of penicillin and the tetracyclines in animal feeds.

Should the agency decide to withdraw approval for these uses of penicillin and the tetracyclines in animal feeds, promulgation of this final rule will have no effect on that action. The placement of a drug in either Category I or II does not affect that drug's potential for development of drug-resistant bacterial. In addition, this final rule will not make withdrawal of approval more difficult by increasing the quantity of those drugs sold for use in feed. Penicillin and the tetracyclines currently do not require an approved medicated feed application and none will be required by this final rule.

8. Six comments were concerned about the safety of imported meat. They stated that, because foreign feed manufacturers and producers are not subject to FDA regulations, domestic feed manufacturers and producers are the subject of unfair discrimination.

The agency does not agree that it is practicing unfair discrimination. Under the act, FDA does not have the authority to inspect foreign medicated feed manufacturers that produce feed for consumption by animals whose edible products are imported into this country. In contrast, Congress mandated that domestic feed manufacturers comply with CGMP regulations, and that they be routinely inspected to determine compliance.

*B. Definitions*

9. Two comments requested that the term "carrier" be deleted from the definition of a Type A medicated article and the term "nutrient" substituted to permit greater latitude in optional ingredients. The comments also requested deletion of the word "other" from § 558.3(b)(1).

The agency does not agree with the first suggestion. The primary purpose of a Type A medicated articles is to provide a source of the drug for use in feed. Deleting the word "carrier" and replacing it with the word "nutrient" would provide an unwarranted emphasis on its nutrient content. The drug carriers used by the manufacturer can include items known to be sources of nutrition. The agency agrees that the word "other" should be deleted, and, accordingly, has revised § 558.3(b)(1).

10. One comment requested that the manufacture of a Type B medicated feed directly from a drug component be permitted rather than first having to produce a Type A medicated article.

The use of a drug component for the manufacture of Type B or Type C medicated feeds is permitted so long as an NADA providing for such manufacture has been approved under section 512(c) of the act. FDA has revised § 558.3(b) to provide for this manufacturing procedure.

11. Two comments stated that § 558.4 should define the concentrations of all drugs that may be used in combination as Type B medicated feeds.

Section 558.4 lists only those drugs and drug combinations that are approved for marketing as Type A medicated articles. Approved Type B combinations are identified in the appropriate regulations for the drugs. Only those specifically listed in the regulations as permitted combinations in Type B medicated feed are permitted.

*C. Current Good Manufacturing Practice*

12. Five comments stated that the requirement in § 225.58 *Laboratory controls*, for retention of results of assays of State feed control officials to fulfill periodic assay requirements, would be prejudicial because only "out of tolerance" results are reported to the firm.

The AAFCO Uniform State Feed Bill, which has been adopted by about half the States, requires that: "The results of all analyses of official samples shall be forwarded by the *DIRECTOR* to the person named on the label and to the purchaser" of the sampled product. In addition, almost all States that have not adopted the AAFCO Uniform State Feed Bill have similar provisions in their laws. Accordingly, State feed control agency officials report all assay results for tested constituents to the person named on the label and the purchaser of the sampled product. The official in some cases does not report the actual laboratory results but indicates that the product meets label guarantees by stating "Pass," "OK," etc. Actual laboratory results are reported on products that do not meet label guarantees. Even though the actual results may not be returned, notification that a product meets guarantees is sufficient to meet the assay requirement of § 225.58. Under these circumstances, the agency does not view this requirement as prejudicial.

13. Several comments stated that the 5 percent assay requirements of § 225.58(b)(2) as proposed in 1981 should be retained.

As discussed in the preamble to the tentative final rule, following an evaluation of the nearly 50 comments addressing this issue, the agency decided that the existing assay requirements would be retained for all products requiring an approved medicated feed application. This consists of at least three representative samples of medicated feed for each drug or drug combination to be assayed annually.

14. Several comments suggested that proposed § 225.135 *Work areas* be changed by adding the words "and storage" to the section.

The agency agrees and has made the revision.

15. Seven comments requested that § 225.142 *Components* be revised because of confusion arising from the use of undefined and imprecise terminology, and an apparent reduction in inventory requirements.

The agency has revised § 225.142 to provide for proper control of incoming

Type A and Type B medicated products. Revised § 225.142 requires an accountability system to assure proper inventory control of the product. The type of system to be used is the choice of the user. The inventory system should be one that provides a record of receipt and eventual use or disposal of the products.

16. Eight comments opposed the language in § 225.180 *Labeling* that would provide cross-references to various parts of the Code of Federal Regulations in which labeling requirements are specified.

The agency has revised § 225.180 to delete reference to specific labeling requirements. Section 225.180 as revised focuses on maintaining the integrity of labeling control and assurance that medicated feeds are appropriately labeled.

*D. Applications*

17. Several comments requested that § 514.1(b) be revised to provide an appropriate cross-reference to § 501.110 (21 CFR 501.110), incorporating the use of collective names. The comments said that the tentative final rule appeared to revoke the use of collective names for nonmedicated feeds.

The agency agrees and has made the suggested change.

18. Several comments requested that § 514.1[b][5][viii][*a*] be clarified to indicate that the method of analysis required applied only to the requested dosage form and not all other possibilities.

The agency agrees and has made the change. In addition, the agency on its own initiatives is revising the analytical method requirement section of the new animal drug application to be consistent with the final rule. The revision provides for references to pharmaceutical dosage products, Type A, Type B, or Type C products. Also, the agency on its own initiative is revising the stability requirement section of the new animal drug application to reflect requirements of the final rule. Section 211.127 (21 CFR 211.137) under CGMP requirements for pharmaceutical dosage forms requires expiration dates on these products. The agency has revised the stability section of the new animal drug application to provide for an expiration date for finished pharmaceutical dosage forms and Type A medicated articles. Section 211.16 requires stability testing for pharmaceutical dosage forms. Section 226.58 requires expiration dates and stability testing for Type A medicated articles. Stability testing of proposed Type B and Type C medicated feeds will be required as part of the new animal drug application for an animal drug.

19. Several comments suggested that all approved medicated feed applications (Form FD 1800) be rescinded and replaced with a new Form FDA 1900.

An approved medicated feed application is a valid license to manufacture a specific medicated feed. FDA may take action to withdraw approval only by following the procedure specified in section 512(m)(4)(B) of the act, and only for the reasons specified in that section. Over the years thousands of applications have been approved for the manufacture of medicated feeds. Any benefit that might be gained by replacing otherwise valid Forms FD 1800 with new Forms FDA 1900 would be far outweighed by the burden imposed on both the public and the agency.

20. Some comments requested that new Form FDA 1900 be made available for comment. Other comments requested that § 514.2 be revised to conform to new Form FDA 1900. One comment submitted a suggested form.

Revised § 514.2 includes all the information submission requirements of Form FDA 1900 and was available for comment. The form suggested by the comment is incomplete because it fails to include all of the elements provided in § 514.2.

21. One comment requested that the words "drug(s) or" in § 514.2(b)(4) be deleted because Form FDA 1900 is only intended for use of a Type A medicated article.

The agency agrees and has made the change.

*D. Miscellaneous Comments*

22. Ten comments noted certain discrepancies in the permitted analytical variations of Type B medicated feeds and stated that in some instances the percentage of variation appeared to be too broad for the concentration of the Type B medicated feed.

After careful consideration, the agency has decided to include the tables used in the 1981 proposal. These tables, which were not part of the 1983 tentative final rule, have been revised to take into account subsequent revisions. The new tables in § 558.4(d) provide for Type A assay limits, Type B maximum use levels (100X or 200X), and Type B and Type C assay limits.

The agency included the Type A assay limits because it believes that this information will be of value to users of medicated articles. The values were not listed in the 1983 tentative final rule, and were incorrectly identified in the 1981 proposed rule as Type B limits. These Type A limits are listed in current Part 558 regulations under the various approved new animal drugs.

The assay limit values listed under Type B and Type C in the final rule reflect the values approved for Type C medicated feeds. Many intermediate premix products (classified as Type B products) also have the same approved limits.

The preamble to the 1981 proposal invited interested persons to submit alternate levels if supported by appropriate analytical data. Many comments were received, but no alternate levels were suggested.

The agency has carefully reviewed the tables and has decided that until sufficient data are received from applicants or other sources, e.g., AAFCO or State government laboratories, the assay limits stated will be used for enforcing potency requirements.

23. A comment from a State agency pointed out that if a Type A medicated article which assays at the lowest value limit is used to manufacture a Type B or Type C medicated feed, the resulting product could be in violation. This occurs due to the wide spread of assay limits between Type A medicated articles and Type B and Type C medicated feeds.

To overcome this possibility, the agency studied the differences between all Type A and Type B and Type C limits. Wherever there was a difference between lower Type A and lower Type C limits of greater than 15 percent, the agency has added a set of intermediate limits for the Type B medicated feed. As an example, bambermycins has premix limits of 90 to 110 percent and finished feed limits of 70 to 130 percent (current § 558.95(c)). Should a Type B medicated feed, which is a finished feed, assaying at the lower limit be used to produce a Type C medicated feed, the latter could be violative. Because of this situation, the agency has established in revised § 558.4(d) intermediate assay limits for a bambermycins Type B feed of 80 to 120 percent. These Type B limits are well within the ranges established for the various Type A medicated articles and Type C medicated feeds and thus can be analyzed by the current methods. FDA will use these limits until applicants can provide data to substantiate other limits. The agency has added a note at the bottom of the tables in § 558.4(d) to describe the need for these additional limits.

24. One comment stated that nonmedicated feeds should be subject to assay requirements to check for cross-contamination.

The agency does not consider this to be a reasonable requirement because of

the number of assays that would be required to analyze each batch of nonmedicated feed for all possible sources for cross-contamination. Should circumstances so require, the agency will analyze feeds, medicated or nonmedicated, for cross-contamination.

25. Two comments requested that § 514.112 be revised to include reference to § 510.515 as a basis for approval.

The agency agrees and has made the change.

26. One comment stated that FDA provided no rationale for the elimination of Category III (the category containing those drugs regulated on a "no-residue" basis or with a "zero" tolerance because of a carcinogenic concern) and urged that FDA retain the 1981 proposal's designation of Category III.

To simplify the program, FDA chose to combine into a single category those drugs previously assigned to Category II and Category III. The definition of Category II now includes all drugs with a withdrawal period as well as those drugs regulated on a "no-residue" basis or with a "zero" tolerance because of a carcinogenic concern. This action will not in any way diminish protection of the public health, but will make the program less complex and its administration more cost-effective.

FDA based this decision on the fact that all of the drugs previously assigned to Category III have withdrawal periods. Because errors associated with the preparation of medicated feed containing a former Category II drug or a former Category III drug would be equally likely to result in animals with above-tolerance residues, the agency concluded that there is no need for a separate Category III.

FDA expanded the 1981 proposal's definition of Category II to ensure that a drug regulated as a carcinogen on a "no-residue" basis in the future would not be assigned to Category I. This action ensures that any carcinogenic new animal drug used in medicated feed will be subject to appropriate controls to protect the public health.

27. One comment stated that the program lacks a scientific rationale and that the agency has failed to make the scientific basis for the proposal available for public comment.

The final rule is based on the agency's conclusion that the entire medicated feeds program should be revised to emphasize regulatory control over those feeds containing new animal drugs that pose the greatest likelihood of producing unsafe residues in the edible products of treated animals. As discussed in the preamble to the tentative final rule, the agency has concluded that the existence or nonexistence of a withdrawal period is a valid basis for making that determination. Although FDA acknowledges that other approaches are possible, FDA has concluded as the expert agency charged with enforcement of the act, that the regulatory scheme in this final rule is the appropriate way to enforce the act's medicated feed provisions.

28. One comment provided data intended to show that the concentration of drug in a product that is intended for further dilution has no significant impact on the accuracy of the concentration of the drug in the final feed.

While the data submitted appear to be valid, the agency does not believe that the data are directly applicable to actual feed manufacturing situations. These data were generated at a research facility using very controlled procedures and equipment that are not typically found on farms or at commercial mills. Therefore, as discussed in paragraph 6 above, the agency continues to believe that the dilution factor is a valid basis on which to determine the safety of a drug used in feed.

29. One comment presented information intended to show that mixer-feeders are inherently safer than commercial feed mills and thus should be exempt from the registration and medicated feed application requirements of the act. The comment contended that inadequate cleaning of equipment was a significant cause of violative residues, and that mixer-feeders are inherently safer than commercial feed mills because each mixer-feeder mixes feed for only one species of animal, thereby eliminating the possibility of cross-contamination with drugs that are not approved for use in that species.

The agency agrees that inadequate cleaning of equipment is a prominent cause of violative residues, as shown by FDA investigations of U.S. Department of Agriculture-reported residue violations in 1977 and 1978. These investigations did not establish, however, that on-the-farm feed-mixing operations are safer than commercial mills. Rather, failure to clean mixing equipment adequately was considered to be a major cause of the residue in a majority of cases involving both mixer-feeders and commercial feed mills. Likewise, the sulfonamide tissue residue problem mentioned by the comment is created by both mixer-feeders and commercial mills, as both types of operations have been found to be contributing in a material way to the problem. Therefore, the agency concludes that exempting mixer-feeders to concentrate its limited resources on commercial mills would not be in the interest of public health.

30. One comment contended that the proposal is contrary to FDA's interpretation of the act concerning unavoidable contamination, and cited sections 306, 406, and 512 of the act (21 U.S.C. 336, 346, and 360b), and 21 CFR 109.7 and 509.7 of the regulations. The comment stated that a substance cannot be unavoidable under the act unless the CGMP regulations are "technology-forcing" so as to provide an incentive for technological improvement.

FDA does not agree that CGMP regulations should be "technology-forcing." CGMP regulations must be flexible because they are applicable to firms that differ widely in size, facilities and equipment used, and products produced. CGMP regulations are designed to be minimum requirements that can reasonably be met by all members of the industry. Although FDA encourages the development and use of improved technology, the agency does not consider the CGMP regulations to be an appropriate mechanism for attaining that goal.

31. One comment stated that FDA had not discussed the legal status of medicated feeds that are contaminated during the mixing process with unintended drugs, and cited section 406 of the act.

FDA regulates the manufacture of medicated feeds, including any contamination by unintended drugs, by means of the CGMP regulations. Because section 406 of the act pertains, in relevant part, to poisonous or deleterious substances added to food that cannot be avoided by good manufacturing practice, it is not applicable to this rulemaking.

32. Three comments stated that the agency had failed to consider adequately the economic consequences of implementation of the program.

An assessment of the economic impact of the program was discussed in the preamble to the 1983 tentative final rule. Copies of the assessment are on file with the Dockets Management Branch for public examination. None of the comments submitted disputed the data used by the agency.

33. Several comments requested changes in the maximum Type B levels for chlortetracycline, dichlorvos, and morantel tartrate. Also, one comment noted that amprolium has a withdrawal time at its lowest approved use in calves and therefore should be a Category II drug.

The agency agrees with the comments and has made the necessary changes. Several other individual drug changes

were made in §§ 558.4 and 558.20. Ethylenediamine dihydriodide was deleted because it is not the subject of an approved NADA or an interim regulation. Fenbendazole was recently approved for use in feed. The maximum Type B level for monensin was increased based upon a new approved use level, and the drug is moved to Category I based upon deletion of its withdrawal period as published in the Federal Register of August 12, 1985 (50 FR 32394). The maximum Type B levels for sulfamethazine and sulfathiazole were changed to eliminate errors in the tentative final rule.

34. Several comments raised concerns about the tentative final rule's 200 grams per ton maximum Type B level for melengestrol acetate. The drug's NADA sponsor pointed out that the 200 grams per ton figure will conflict with the drug's conditions of approval.

The agency agrees. Therefore, the maximum Type B level is 2 grams per ton (0.00022 percent), which is the level currently exempted.

## IV. Implementation Procedures

A program alteration of the magnitude presented in this final rule cannot be immediately placed into effect. For example, it may be necessary for existing stocks to be depleted, decisions of management to be made, medicated feed applications to be submitted, and inspections to be completed. Therefore, these regulations shall become effective May 2, 1986, except that the provisions of 21 CFR 558.4(d), Category II, requiring the submission and approval of medicated feed applications for products formerly exempt from such requirement shall become effective March 3, 1987.

As an example of the effect of this program, two drug examples are presented. The first example is a drug (salinomycin) which was not previously exempt but which is exempt under the new program. The second example covers a previously exempt drug (roxarsone) which becomes nonexempt under the new program.

1. *Salinomycin.* Salinomycin, a recently approved poultry drug, now requires an approved medicated feed application to cover its use in the manufacture of medicated feed. Because this drug has no withdrawal period, after May 2, 1986, the use of salinomycin Type A medicated articles in the manufacture of Type B or Type C medicated feeds will no longer require an approved application (Form FDA 1900). Previously approved applications for this drug will be retired. FDA will return to the applicant those applications currently under review for salinomycin with a letter explaining its action.

2. *Roxarsone.* The agency has not required approved medicated feed applications for roxarsone (§ 558.530(c)). However, with its placement in Category II, because the drug requires a withdrawal period, the use of Type A medicated articles containing roxarsone in the manufacture of Type B or Type C medicated feeds will require approved medicated feed applications. Should a medicated feed manufacturer decide to use the roxarsone Type A medicated article, then the following will need to be accomplished before March 3, 1987: (1) Register with the agency as a drug manufacturer (if not registered previously) using Form FDA 2656, which can be obtained from the Food and Drug Administration, Center for Drugs and Biologics, Drug Listing Staff (HFN–315), 5600 Fishers Lane, Rockville, MD 20857; and (2) obtain approved medicated feed applications. Because FDA has 90 days to review these applications, the agency recommends that applications for roxarsone and other formerly exempt drugs be submitted by December 3, 1986. In fact, the agency requests that firms submit their applications for these drugs as soon as possible following the effective date of these regulations to facilitate an orderly transition to the new program.

In the preamble to the 1981 proposal, the agency announced a modified directed inspection program. The program was intended to permit more efficient use of agency resources in determining whether firms manufacturing medicated feed are in compliance with key CGMP regulations. The proposal also indicated that directed inspections would continue until a final rule was published. Following publication of this final rule, the agency will revise its medicated feed compliance program to direct the inspectors (FDA or State) to determine compliance with the full range of CGMP regulations. The depth of an inspection will depend on such factors as previous inspectional history and current inspectional findings.

Firms may apply to FDA for approval under section 512(m) of the act using the new Form FDA 1900. (Copies of this form may be obtained from the Public Health Service Forms and Publication Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857.) Firms not in compliance with the CGMP regulations will have their applications denied. FDA intends to schedule and conduct preapproval inspection before final agency action on applications from firms with no inspectional history.

The agency also indicated in the preamble to the 1981 proposal its intention to consider whether further administrative and regulatory action should be initiated against firms that failed the directed inspections. After careful consideration, the agency has decided to propose withdrawal of their medicated feed applications (Form FDA 1800) for Category II drugs through formal procedures under section 512(m)(4) of the act following publication of this final rule. Firms that desire to continue using the nonexempt drug products may request reinspection after they have corrected the deficiencies in their operations.

Because the existing approved medicated feed applications (Form FDA 1800) constitute licenses, they cannot be "canceled" as recommended by the Medicated Feed Task Force. As indicated above, the agency will initiate action to withdraw applications for Category II drugs, where the firm has been found not to be in compliance with CGMP regulations. Because the use of Category I, Type A medicated articles in the manufacture of Type B or Type C medicated feeds no longer requires an approved application, these applications are moot. Therefore, the agency will retire them administratively.

## V. Economic Impact

The recategorization of many drugs used in animal feeds will have small but differing cost impacts on the various sectors of the industry. For each of the industry sectors analyzed, the costs imposed by this revision of the proposed medicated feed program are well below the thresholds that signify a major rule according to the criteria specified in Executive Order 12291. Thus, the agency has determined that these final regulations are not a major rule.

Most small livestock and poultry farms do not manufacture the medicated feeds that they use and therefore would not be affected. Thus, the changes will affect larger farms, and even there the impacts will be small. A large cattle feedlot or integrated chicken farm is estimated to save an average of about $585 annually (a total of $400,000) because the drugs most commonly used would be subject to less regulation. An average large hog producer is estimated to have added costs of about $14 (a total of $427,000), if the most commonly used drugs continue their popularity. FDA was unable to estimate the direction of the impact on turkey producers, but expects the total impact to be smaller than either of the amounts cited above.

The agency expects that there may be some shifting among drugs used by

livestock producers (particularly the hog producers) if it becomes economically advantageous to substitute alternative drugs for those currently used. While such shifts were not projected, they would serve to mitigate any added costs.

In the nonfarm sector, an average commercial feed mill should experience savings of about $49 (a total of $470,000) under the revised program. Further, as many as 1,150 commercial feed mills may choose to use only those drugs for which medicated feed applications would not be required and would thereby voluntarily avoid further regulation (a savings of $630,000). No significant net impact is expected for animal drug manufacturers, although some shifts in market shares are possible.

For each of the industry sectors analyzed, any costs imposed by this revision of the medicated feed program would be well below the thresholds that signify a major rule according to the criteria specified in Executive Order 12291. Thus, the agency has determined that the final rule does not constitute a major rule under that Order.

FDA has considered the effect that this final rule will have on small entities, including small businesses, and certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will result.

A threshold assessment supporting these conclusions is available for review in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

### VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### VII. Paperwork Reduction Act of 1980

The information collection requirements contained in §§ 225.202, 514.1(b)(3)(v)(*a*) and (*b*) and (5)(vii)(*a*), and 514.2(a) and (b) were submitted to the Office of Management and Budget (OMB) with the tentative final rule as required by section 3504(h) of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). As a result of its review, OMB approved these requirements during the proposed rulemaking stage and assigned control number 0910–0163. FDA has incorporated these requirements into the appropriate Code of Federal Regulations sections bearing OMB control numbers as shown in the table below:

| Section | OMB Control No. |
|---|---|
| 225.202 | 0910–0152 |
| 514.1(b)(3)(v) (*a*) and (*b*) and (5)(vii)(*a*) | 0910–0032 |
| 514.2(a) and (b) | 0910–0011 |

### List of Subjects

*21 CFR Part 207*

Drug listing, Drug registration.

*21 CFR Part 210*

Drugs, Packaging and containers.

*21 CFR Part 225*

Animal drugs, Animal feeds, Labeling, Packaging and containers.

*21 CFR Part 226*

Animal feed premixes, Labeling, Packaging and containers.

*21 CFR Part 510*

Administrative practice and procedure; Animal drugs, Labeling, Reporting requirements.

*21 CFR Part 514*

Administrative practice and procedure, Animal drugs.

*21 CFR Part 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Parts 207, 210, 225, 226, 510, 514, and 558 are amended as follows:

## PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR Part 207 is revised to read as follows:

**Authority:** Secs. 201, 502, 505, 506, 507, 510, 512, 701(a), 704, Pub. L. 717, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055, 1057 as amended (21 U.S.C. 321, 352, 355, 356, 357, 360, 360b, 371(a), 374); sec. 351, Pub. L. 410, 58 Stat. 702 as amended (42 U.S.C. 262); 21 CFR 5.10, 5.11.

2. Part 207 is amended in § 207.10 by revising paragraph (f), to read as follows:

**§ 207.10 Exemptions for domestic establishments.**

* * * * *

(f) Persons who manufacture Type B or Type C medicated feed using Category I, Type A medicated articles; Category I, Type B medicated feeds; and/or Category II, Type B medicated feeds, as defined in § 558.3 of this chapter, as drug sources.

* * * * *

## PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

3. The authority citation for 21 CFR Part 210 is revised to read as follows:

**Authority:** Secs. 501, 701, 52 Stat. 1049–1050 as amended, 1055–1056 as amended (21 U.S.C. 351, 371); 21 CFR 5.10, 5.11.

4. Part 210 is amended by revising the part heading as set out above.

5. In § 210.3 by revising paragraph (b)(13) and (14), to read as follows:

**§ 210.3 Definitions.**

* * * * *

(b) * * *

(13) The term "medicated feed" means any Type B or Type C medicated feed as defined in § 558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of Part 225 of this chapter.

(14) The term "medicated premix" means a Type A medicated article as defined in § 558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of Part 226 of this chapter.

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## PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

6. The authority citation for 21 CFR Part 225 is revised to read as follows:

**Authority:** Secs. 501, 512, 701(a), 52 Stat. 1049–1050 as amended, 1055, 82 Stat. 343–351 (21 U.S.C. 351, 360(b), 371(a)); 21 CFR 5.10, 5.11.

7. Part 225 is amended in § 225.1 by revising paragraph (b), to read as follows:

**§ 225.1 Current good manufacturing practice.**

* * * * *

(b)(1) The provisions of this part set forth the criteria for determining whether the manufacture of a medicated feed is in compliance with current good manufacturing practice. These regulations shall apply to all types of facilities and equipment used in the production of medicated feeds, and they shall also govern those instances in

which failure to adhere to the regulations has caused nonmedicated feeds that are manufactured, processed, packed, or held to be adulterated. In such cases, the medicated feed shall be deemed to be adulterated within the meaning of section 501(a)(2)(B) of the act, and the nonmedicated feed shall be deemed to be adulterated within the meaning of section 402(a)(2)(D) of the act.

(2) The regulations in §§ 225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed application is required. The regulations in §§ 225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which approved medicated feed applications are not required.

8. In § 225.58 by revising "FD–1800" to read "FDA 1900" in paragraph (b)(1), by removing and reserving paragraph (b)(2), and by revising paragraph (c), to read as follows:

**§ 225.58 Laboratory controls.**

* * * * *

(b) * * *

(2) [Reserved]

(c) The originals or copies of all results of assays, including those from State feed control officials and any other governmental agency, shall be maintained on the premises for a period of not less than 1 year after distribution of the medicated feed. The results of assays performed by State feed control officials may be considered toward fulfillment of the periodic assay requirements of this section.

* * * * *

**§ 225.115 [Amended]**

9. In § 225.115 *Complaint files* in paragraph (b)(2) by revising the two references to "FD–1800" to read "FDA 1900".

10. By adding new Subparts F, G, H, and I, to read as follows:

**Subpart F—Facilities and Equipment**

Sec.
225.120 Building and grounds.
225.130 Equipment.
225.135 Work and storage areas.

**Subpart G—Product Quality Assurance**

225.142 Components.
225.158 Laboratory assays.
225.165 Equipment cleanout procedures.

**Subpart H—Labeling**

225.180 Labeling.

**Subpart I—Records**

225.202 Formula, production, and distribution records.

**Subpart F—Facilities and Equipment**

**§ 225.120 Buildings and grounds.**

Buildings used for production of medicated feed shall provide adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

**§ 225.130 Equipment.**

Equipment shall be capable of producing a medicated feed of intended potency and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction, precision, and accuracy for their intended purposes. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of cleanout procedure(s).

**§ 225.135 Work and storage areas.**

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved for use in the manufacture of animal feed.

**Subpart G—Product Quality Assurance**

**§ 225.142 Components.**

Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B medicated feeds shall be used in accordance with their labeled mixing directions.

**§ 225.158 Laboratory assays.**

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

**§ 225.165 Equipment cleanout procedures.**

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

**Subpart H—Labeling**

**§ 225.180 Labeling.**

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

**Subpart I—Records**

**§ 225.202 Formula, production, and distribution records.**

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

(Information collection requirements approved by the Office of Management and Budget under number 0910–0152.)

## PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

11. The authority citation for 21 CFR Part 226 is revised to read as follows:

**Authority:** Secs. 501, 701, 52 Stat. 1049–1050 as amended, 1055–1056 as amended (21 U.S.C. 351, 371); 21 CFR 5.10, 5.11.

12. Part 226 is amended by revising the part heading as set out above.

13. By revising the term "medicated premixes" to read "Type A medicated article(s)" wherever it appears in Part 226.

## PART 510—NEW ANIMAL DRUGS

14. The authority citation for 21 CFR Part 510 continues to read as follows:

**Authority:** Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

**§ 510.6 [Amended]**

15. Part 510 is amended in § 510.6 *New animal drugs; transitional provisions re section 512 of the Act* in paragraphs (d)(3), (e), and (f) by revising "FD–1800" to read "FDA 1900".

**§ 510.305 [Amended]**

16. § 510.305 *Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs* in the introductory text and in paragraph (a) by revising "FD–1800" to read "FD 1900".

## PART 514—NEW ANIMAL DRUG APPLICATIONS

17. The authority citation for 21 CFR Part 514 is revised to read as follows:

Authority: Secs. 512(i), (n), 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b(i), (n), 371(a)); 21 CFR 5.10, 5.11.

18. Part 514 is amended in § 514.1 by removing paragraph (e), by adding a parenthetical statement at the end of the section, and by revising paragraph (b)(3)(v)(*a*) and (*b*) and (5)(vii)(*a*) and (5)(x), to read as follows:

**§ 514.1. Applications.**

* * * * *

(b) * * *

(3) * * *

(v) * * *

(*a*) Specimens of labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested in any of the labeling, including advertising, sponsored by the applicant. Ingredient labeling may utilize collective names as provided in § 501.110 of this chapter.

(*b*) Representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug.

* * * * *

(5) * * *

(vii) * * *

(*a*) A description of practicable methods of analysis of adequate sensitivity to determine the amount of the new animal drug in the final dosage form should be included. The dosage form may be a finished pharmaceutical product, a Type A medicated article, a Type B or a Type C medicated feed, or a product for use in animal drinking water. Where two or more active ingredients are included, methods should be quantitative and specific for each active ingredient.

* * * * *

(x) A complete description of, and data derived from, studies of the stability of the new animal drug in the final dosage form, including information showing the suitability of the analytical methods used. A description of any additional stability studies underway or planned. Stability data for the finished dosage form of the new animal drug in the container in which it is to be marketed, including any proposed multiple dose container, and, if it is to be put into solution at the time of dispensing, for the solution prepared as directed. If the new animal drug is intended for use in the manufacture of Type C medicated feed as defined in § 558.3 of this chapter, stability data derived from studies in which representative formulations of the medicated feed articles are used. Similar data may be required for Type B medicated feeds as determined by the Food and Drug Administration on a case-by-case basis. Expiration dates shall be proposed for finished pharmaceutical dosage forms and Type A medicated articles. If the data indicate that an expiration date is needed for Type B or Type C medicated feeds, the applicant shall propose such expiration date. If no expiration date is proposed for Type B or Type C medicated feeds, the applicant shall justify its absence with data.

* * * * *

(Information collection requirements approved by the Office of Management and Budget under number 0910–0032.)

19. By revising § 514.2, to read as follows:

**§ 514.2 Applications for animal feeds bearing or containing new animal drugs.**

(a) Applications (Form FDA 1900) to be filed under section 512(m) of the act shall be completed, signed, and submitted in triplicate in the form described in paragraphs (b) and (c) of this section.

(b) Each application for a Type B or Type C medicated feed, as defined in § 558.3 of this chapter, shall include the following information:

(1) The name and address of the applicant.

(2) The registration number assigned pursuant to section 510 of the act and last date of registration of each mill.

(3) Whether the submission is an original or supplemental application.

(4) Identification of the Type A medicated article, as defined in § 558.3 of this chapter, used by generic name, potency, and manufacturer.

(5) The species of animal(s) for which the feed is intended.

(6) The form of feed to be produced, i.e., mash, meal crumbles, pellets, liquid, or other specified form.

(7) Whether the feed is a Type B or Type C medicated feed.

(8) Whether the feed is for sale or for own use (not for sale).

(9) Level of the drug(s) in the finished feed, and the amount of Type A medicated article per ton contained therein.

(10) Identification of the regulation(s) in Subchapter E of this chapter on which approval relies.

(11) Labeling representative of each intended use as stated in the claim. Each generic label shall include the claim, drug level, mixing directions, feeding directions, caution and/or warning statements, and any other special directions required by the published regulation. This shall consist of bag labels, invoice copy, bulk labels, and placards when applicable.

(12) A commitment to establish and maintain a program of sampling and analysis consisting of an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the date of manufacture of the medicated feed.

(13) A statement of the minimum and maximum assay value permitted from the labeled amount of the drug.

(14) Identification of the agent authorized to act on behalf of the applicant.

(15) The applicant's name, responsible individual's title and original signature, and date.

(c) Upon approval, one copy of the application will be signed by an authorized employee of the Food and Drug Administration designated by the Commissioner, and it will be returned to the applicant.

(Information collection requirements approved by the Office of Management and Budget under number 0910–0011.)

**§ 514.9 [Amended]**

20. In § 514.9 *Supplemental applications for animal feeds bearing or containing new animal drugs* in paragraph (c) by revising "FD–1800" to read "FDA 1900".

**§ 514.55 [Amended]**

21. In § 514.55 *Forms for certification or exemption of antibiotic drugs for animal use subject to section 512(n) of the Act* by revising "1800" to read "1900" and by revising "FD–1800—Revised" to read "FDA 1900".

**§ 514.105 [Amended]**

22. In § 514.105 *Approval of applications* in paragraph (b) by revising "FD–1800" to read "Form FDA 1900".

23. By adding new § 514.112, to read as follows:

**§ 514.112 Return of applications for animal feeds bearing or containing new animal drugs.**

Applications submitted pursuant to § 514.2 will be returned to the applicant if such applications are incomplete or inaccurate or do not contain an identification of the applicable regulation(s). These regulations include those published pursuant to section 512(i) of the act, and are found in Part 558 of this chapter. In addition, § 510.515 of this chapter may also provide a basis on which approval of the application relies, as required by § 514.2(b)(10). All reasons for the return of the application will be made known to the applicant.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

24. The authority citation for 21 CFR Part 558 continues to read as follows:

**Authority:** Sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

25. Part 558 is amended by revising § 558.3, to read as follows:

**§ 558.3 Definitions and general considerations applicable to this part.**

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved or are regulated on a "no-residue" basis or with a "zero" tolerance because of a carcinogenic concern regardless whether a withdrawal period is required.

(2) A "Type A medicated article" is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105(a) of this chapter.

(3) A "Type B medicated feed" is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight of the Type A medicated article. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term "highest continuous use level" means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires an application approved under § 514.105(b) of this chapter.

(4) A "Type C medicated feed" is intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) on or offered "free-choice" (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires an application approved under § 514.105(b) of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or "drum-run" (dried crude fermentation product)) requires an application approved under § 514.105(a) of this chapter.

26. By revising § 558.4, to read as follows:

**§ 558.4 Medicated feed applications.**

(a) The manufacture of a Type B or Type C medicated feed from a Category I, Type A medicated article is exempt from the requirement of an approved medicated feed application.

(b) The manufacture of a Type B or Type C medicated feed from a Category II, Type A medicated article requires an approved medicated feed application.

(c) The use of Type B and Type C medicated feeds shall conform to the conditions of use provided for in Subpart B of this part and in §§ 510.515, 558.15, and 558.20.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

CATEGORY I

| Drug | Assay limits type A percent [1] | Type B maximum (200x) | Assay limits (percent of labeled amount) type B/C [2] |
|---|---|---|---|
| Aklomide | 90–110 | 22.75 g/lb (5.0 %) | 85–120. |
| Ammonium chloride | 90–110 | 4.0 oz/lb (25 %) | 85–120. |
| Amprolium with Ethopabate | 94–114 | 22.75 g/lb (5.0 %) | 80–120. |
| Bacitracin methylene disalicylate | 85–115 | 20.0 g/lb (4.4 %) | 70–130. |
| Bacitracin zinc | 84–115 | 5.0 g/lb (1.1 %) | 74–130. |
| Bambermycins | 90–110 | 800 g/ton (0.09 %) | 80–120/170–130. |
| Buquinolate | 90–110 | 9.8 g/lb (2.2 %) | 80–120. |
| Chlortetracycline | 95–125 | 40.0 g/lb (8.8 %) | 80–115/170–130. |
| Coumaphos | 95–115 | 6.0 g/lb (1.3 %) | 80–120. |
| Decoquinate | 90–105 | 2.72 g/lb (0.6 %) | 80–120. |
| Dichlorvos | 100–115 | 33.0 g/lb (7.3 %) | 90–120/80–130. |
| Erythromycin (thiocyanate salt) | 85–115 | 9.25 g/lb (2.04 %) | <20g/ton 70–115/50–150; >20g/ton 75–125. |
| Fenbendazole | 95–113 | 4.54 g/lb (1.0 %) | 75–125. |
| Iodinated casein | 85–115 | 20.0 g/lb (4.4 %) | 75–125. |

CATEGORY I—Continued

| Drug | Assay limits type A percent [1] | Type B maximum (200x) | Assay limits (percent of labeled amount) type B/C [2] |
|---|---|---|---|
| Monensin | 90–110 | 40.0 g/lb (8.8 %) | Chickens: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Liq. feed: 80–120. |
| Nequinate | 95–112 | 1.83 g/lb (0.4 %) | 80–120. |
| Niclosamide | 85–20 | 225 g/lb (49.5 %) | 80–120. |
| Nystatin | 85–115 | 5.0 g/lb (1.1 %) | 75–125. |
| Oleandomycin | 85–120 | 1.125 g/lb (0.25 %) | <11.25 g/ton 70–130; >11.25 g/ton 75–125. |
| Oxytetracycline | 90–120 | 20.0 g/lb (4.4 %) | 75–125/65–135. |
| Penicillin | 80–120 | 10.0 g/lb (2.2 %) | 65–135. |
| Penicillin Streptomycin | 80–120 | 1.5 g/lb (0.33 %) | 65–135. |
| | 85–115 | 7.5 g/lb (1.65 %) | 70–130. |
| Poloxalene | 90–110 | 54.48 g/lb (12.0 %) | Liq. feed: 85–115. |
| Salinomycin | 100–120 | 6.0 g/lb (1.3 %) | 80–120 |
| Tylosin | 80–120 | 10.0 g/lb (2.2 %) | 75–125. |
| Virginiamycin | 85–115 | 10.0 g/lb (2.2 %) | 70–130. |
| Zoalene | 98–104 | 11.35 g/lb (2.4 %) | 85–115. |

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

CATEGORY II

| Drug | Assay limits type A percent [1] | Type B Maximum (100x) | Assay limits (percent of labeled amount) type B/C [2] |
|---|---|---|---|
| Amprolium | 94–114 | 11.35 g/lb (2.5%) | 80–120. |
| Arsanilate sodium | 98–108 | 4.5 g/lb (1.0%) | 85–115/75–125. |
| Arsanilic acid | 98–108 | 4.5 g/lb (1.0%) | 85–115/75–125. |
| Butynorate | 90–110 | 17.0 g/lb (3.74%) | 85–115. |
| Butynorate | 90–110 | 63.45 g/lb (14.0%) | 85–115. |
| Piperazine | 90–110 | 49.85 g/lb (11.0%) | 85–115 |
| Phenothiazine | 90–110 | 263.32 g/lb (58.0%) | 85–115. |
| Carbadox | 90–110 | 2.5 g/lb (0.55%) | 75–125 |
| Carbarsone | 93–102 | 17.0 g/lb (3.74%) | 85–115. |
| Clopidol | 94–106 | 11.4 g/lb (2.5%) | 90–115/80–120. |
| Dimetridazole | 96–103 | 9.1 g/lb (2.0%) | 85–120. |
| Famphur | 100–110 | 5.5 g/lb (1.21%) | 90–115/80–120. |
| Furazolidone | 95–105 | 10.0 g/lb (2.2%) | 85–115. |
| Halofuginone hydrobromide | 80–120 | 272.0 g/ton (.03%) | 70–125. |
| Hygromycin B | 90–110 | 1,200 g/ton (0.13%) | 75–125. |
| Ipronidazole | 98–115 | 2.84 g/lb (0.63%) | 0.00625%, 85–120/75–125; 0.025%, 85–120/80–120. |
| Lasalocid | 100–120 | 5.65 g/lb (1.24%) | Chickens: 85–120/75–125; Supplements: 85–120/80–120. |
| Levamisole | 85–120 | 113.5 g/lb (25%) | 85–125. |
| Lincomycin | 90–115 | 10.0 g/lb (2.2%) | 80–130. |
| Melengestrol acetate | 90–110 | 2.0 g/ton (0.00022%) | 80–115/70–120. |
| Morantel tartrate | 90–110 | 66.0 g/lb (14.52%) | 85–115. |
| Neomycin | 80–120 | 7.0 g/lb (1.54%) | 70–125. |
| Neomycin | 80–120 | 7.0 g/lb (1.54%) | 70–125. |
| Oxytetracycline | 80–120 | 10.0 g/lb (2.2%) | 65–135. |
| Nicarbazin | 98–106 | 5.675 g/lb (1.25%) | 85–115/80–120. |
| Nitarsone | 90–110 | 8.5 g/lb (1.87%) | 85–120. |
| Nitrofurazone | 90–110 | 10.0 g/lb (2.2%) | 80–125. |
| Nitromide | 90–110 | 11.35 g/lb (2.5%) | 80–120. |
| Sulfanitran | 85–115 | 13.6 g/lb (3.0%) | 75–125. |
| Nitromide | 90–110 | 11.35 g/lb (2.5%) | 85–115. |
| Sulfanitran | 85–115 | 5.65 g/lb (1.24%) | 75–125. |
| Roxarsone | 95–103 | 2.275 g/lb (0.5%) | 85–120. |
| Novobiocin | 85–115 | 17.5 g/lb (3.85%) | 80–120. |
| Phenothiazine | 90–110 | 66.5 g/lb (14.6%) | 85–115. |
| Piperazine | 90–110 | 165 g/lb (40.25%) | 85–115. |
| Pyrantel tartrate | 90–110 | 4.8 g/lb (1.1%) | 85–115. |
| Robenidine | 95–115 | 1.5 g/lb (0.33%) | 80–120. |
| Ronnel | 85–115 | 27.2 g/lb (6.0%) | 80–120. |
| Roxarsone | 95–103 | 2.275 g/lb (0.5%) | 85–120. |
| Roxarsone | 95–103 | 2.275 g/lb (0.5%) | 85–120. |
| Aklomide | 90–110 | 11.35 g/lb (2.5%) | 85–120. |
| Roxarsone | 95–103 | 2.275 g/lb (0.5%)( | 85–120. |
| Clopidol | 94–106 | 11.35 g/lb (2.5%) | 80–120. |
| Bacitracin methylene disalicylate | 85–115 | 5.0 g/lb (1.1%) | 70–130. |
| Roxarsone | 95–103 | 2.275 g/lb (0.5%) | 85–120. |
| Monensin | 90–110 | 5.5 g/lb (1.2%) | 75–125. |
| Sulfadimethoxine | 95–115 | 5.675 g/lb (1.25%) | 0.01% (combined) 85–115/75–125. |
| Ormetoprim | 95–115 | 3.405 g/lb (0.75%) | 0.02% (combined) 85–115. |
| Sulfaethoxy-pyridazine | 95–105 | 50.0 g/lb (11.0%) | 85–115. |
| Sulfamerazine | 85–115 | 18.6 g/lb (4.0%) | 85–115. |
| Sulfamethazine | 85–115 | 10.0 g/lb (2.2%) | 80–120. |
| Chloretetracycline | 95–125 | 10.0 g/lb (2.2%) | 85–125/70–130. |
| Penicillin | 80–120 | 5.0 g/lb (1.1%) | 85–125/70–130. |
| Sulfamethazine | 85–115 | 10.0 g/lb (2.2%) | 80–120. |
| Chlortetracycline | 95–125 | 10.0 g/lb (2.2%) | 85–125/70–130. |
| Sulfamethazine | 85–115 | 10.0 g/lb (2.2%) | 80–120. |
| Tylosin | 80–120 | 10.0 g/lb (2.2%) | 75–125. |

CATEGORY II—Continued

| Drug | Assay limits type A percent [1] | Type B Maximum (100x) | Assay limits (percent of labeled amount) type B/C [2] |
|---|---|---|---|
| Sulfanitran | 85–115 | 13.6 g/lb (3.0%) | 75–125. |
| Aklomide | 90–110 | 11.2 g/lb (2.5%) | 85–120. |
| Sulfanitran | 85–115 | 13.6 g/lb (3.0%) | 75–125. |
| Aklomide | 90–110 | 11.2 g/lb (2.5%) | 85–120. |
| Roxarsone | 95–103 | 2.715 g/lb (0.60%) | 85–120. |
| Sulfanitran | 85–115 | 13.6 g/lb (3.0%) | 75–125. |
| Aklomide | 90–110 | 11.2 g/lb (2.5%) | 85–120. |
| Roxarsone | 95–103 | 2.27 g/lb (0.5%) | 85–120. |
| Sulfaquinoxaline | 98–106 | 11.2 g/lb (2.5%) | 85–115. |
| Sulfathiazole | 85–115 | 10.0 g/lb (2.2%) | 80–120. |
| Chlortetracycline | 85–125 | 10.0 g/lb (2.2%) | 70–130. |
| Penicillin | 80–120 | 5.0 g/lb (1.1%) | 70–130. |
| Thiabendazole | 94–106 | 45.4 g/lb (10.0%) | <7% 85–115; <7% 90–110. |

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

27. In §558.15 by revising the introductory text of paragraph (g) and the introductory text of paragraph (g)(2), to read as follows:

**§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.**

* * * * *

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article that is produced solely from another Type A medicated article that is in compliance with the requirements of this section. Provided, that the diluted Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A medicated article is approved by regulation in this part.

* * * * *

(2) The following is a list of drug combinations permitted when prepared from Type A medicated articles listed in paragraph (g)(1) of this section. Drug combination and sponsors listed in Subpart B of this part are incorporated herein by reference because the drug combinations are safe and effective by contemporary standards, or their sponsors have been notified of any additional safety or efficacy data required on an individual basis:

* * * * *

28. By adding new §558.20 to Subpart A, to read as follows:

**§ 558.20 Drugs used in medicated feeds in use before January 1, 1958, which are not otherwise listed; interim listing.**

Applications for animal feeds bearing or containing new animal drugs shall contain a reference to a section in the new animal drug regulations where the drug and the intended use are listed. For the purposes of such applications the following list identifies drugs that are required to be the subject of approved medicated feed applications for the indicated uses which are not listed in other new animal drug regulations. The drugs are not listed elsewhere for these uses in other new animal drug regulations because they were so used prior to the Food Additives Amendment of 1958 which required the listing of such drugs in appropriate regulations.

| Drug ingredient | Species | Use levels | Indications for use | Limitations |
|---|---|---|---|---|
| Arsanilate sodium | Swine | 0.005 to 0.01% | Increase rate of gain and improve feed efficiency in growing swine. | Withdraw 5 days before slaughter. As sole source of organic arsenic. |
| Do | do | 0.01% | Control of swine dysentery (hemorrhagic enteritis, bloody dysentery). | Withdraw 5 days before slaughter. Feed continuously as sole source of organic arsenic. |
| Do | do | 0.025 to 0.04% | Treatment of swine dysentery (hemorrhagic enteritis, bloody dysentery). | Withdraw 5 days before slaughter. Feed for 5–6 days as sole source of organic arsenic. |
| Arsanilic acid | do | 0.005 to 0.01% | Increase rate of gain and improve feed efficiency in growing swine. | Withdraw 5 days before slaughter. As sole source of organic arsenic. |
| Do | do | 0.01% | Control of swine dysentery (hemorrhagic enteritis, bloody dysentery). | Withdraw 5 days before slaughter. Feed continuously as sole source of organic arsenic. |
| Do | do | 0.025 to 0.04% | Treatment of swine dysentery (hemorrhagic enteritis, bloody dysentery). | Withdraw 5 days before slaughter. Feed for 5–6 days as sole source of organic arsenic. |
| Butynorate (dibutytin dilaurate). | Turkeys | 0.0375% | As an aid in the prevention of coccidiosis (caused by *E. meleagridis, E. meleagrimitis, E. gallopavonis*) and hexamitiasis. | Withdraw 7 days before slaughter. |
| Neomycin sulfate | Chickens, turkeys, and ducks. | 70 to 140 g/ton of complete feed as neomycin base. | For treatment of bacterial enteritis (nonspecific enteritis, salmonellosis, bluecomb, mud fever). | Withdrawal before slaughter: 30 days, cattle; 20 days, sheep and swine; 14 days, turkeys, ducks, and laying hens; 5 days, broiler chickens. |
| Do | Mink | 140 g/ton of complete feed as neomycin base. | For treatment of bacterial enteritis and diarrhea | Do. |
| Do | Swine, calves, cattle, horses, sheet, goats. | 70 to 140 g/ton of complete feed as neomycin base. | For treatment of bacterial enteritis (scours, diarrhea, bloody dysentery, vibrionic dysentery, winter dysentery, white scours, coli-bacillosis, salmonellosis, diarrhea caused by *E. coli*, vibrio and salmonella organisms); enterotoxemia in lambs. | Do. |
| Nitarsone (4-nitrophenyl-arsonic acid). | Chickens and turkeys. | 0.01875% | As an aid in the prevention of blackhead | Withdraw 5 days before slaughter. As sole source of organic arsenic. |
| Phenothiazine | Chickens | 0.5 g per bird | Removal of cecal worms *Heterakis gallinarum*) | For 1 day only. |
| Do | Turkeys | 1 g per bird | do | Do. |
| Do | Swine | 5 g up to 25 lb; 8 g, 26 to 50 lb; 10 g, 51 to 100 lb; 20 g, 101 to 200 lb; 30 g, 201 lb and up. | Removes nodular worms (*Oesophagostomum*) | Do. |

| Drug ingredient | Species | Use levels | Indications for use | Limitations |
|---|---|---|---|---|
| Do | Sheep and goats | 20 to 60 lb body weight, 12.5 g; over 60 lb body weight, 25 g. | Removal of stomach worms (*Haemonchus, Osteragia,* and *Trichostrongylus* spp.); large-mouth bowel worms (*Chabertia* spp.), and hookworms (*Bunostomum* spp.). | Milk from dairy animals which have been treated with phenothiazine should not be used for food for 4 days following treatment. |
| Do | do | 1g/head/day | Control of stomach worms (*Haemonchus, Osteragia,* and *Trichostrongylus* spp.); large-mouth bowel worms and hookworms (*Chabertia* spp.), (*Bunostomum* spp.). | Do not feed to lactating dairy animals. Feed continuously. |
| Do | Cattle | 10 g/100 lb body weight, up to a maximum of 70 g. | Removes common stomach worms *Haemonchus*), lesser stomach worms (*Ostertagia*), hair worms, bankrupt worms (*Trichostrongylus* spp.), nodular worm (*Oesophagostomum* spp.), and largemouth bowel worms (*Chabertia* spp.). | Milk from dairy animals which have been treated with phenothiazine should not be used for food for 4 days following treatment. |
| Do | do | 20 g/100 lb body weight up to a maximum of 80 g. Micronized (2-3 micron size particles)—10 g/100 lb body weight, up to a maximum of 60 g. | Hookworms (*Bunostomum* spp.) | For 1 day only. Milk from dairy animals which have been treated with phenothiazine should not be used for food for 4 days following treatement. |
| Do | do | 0.25 g/100 lb body weight/day. For adult average dose is 2 g. | Controls common stomach worms (*Haemonchus*), lesser stomach worms (*Ostertagia*), hair worms, bankrupt worms (*Trichostrongylus* ssp.), nodular worm (*Oesophagostomum* spp.), and largemouth bowel worms (*Chabertia* spp.). | Do not feed to lactating dairy animals. |
| Do | Horses and mules | 2.5 g/100 lb body weight up to a maximum of 30 g. | Removal of strongyles (*Strongylus* spp.) | For 1 day only. |
| Do | do | 2 g per head per day | do | For continuous use; feed 2 g per head per day for 21 consecutive days then none for 9 days. Repeat the feeding schedule as long as worm control is desired. |
| Piperazine | Chickens (under 6 weeks of age). | 0.2 to 0.4% | Control of infestation of large roundworms (*Ascaris*) | As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100 mg of piperazine per bird. |
| Do | Chickens (over 6 weeks of age). | do | do | As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100 mg of piperazine per bird. |
| Do | Turkeys (under 12 weeks of age). | do | do | As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100 mg of piperazine per bird. |
| Do | Turkeys (over 12 weeks of age). | do | do | As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100–400 mg of piperazine per bird according to size. |

29. In § 558.35, by removing paragraphs (a), (b), (d), and (e), by redesignating paragraph (c) as paragraph (a) and revising the introductory text of the redesignating paragraph, and by redesignated existing paragraphs (f) and (g) as paragraphs (b) and (c), respectively, to read as follows:

**§ 558.35 Aklomide.**

(a) *Approvals.* Type A medicated articles: to 017210 in § 510.600(c) of this chapter, as follows:

* * * * *

30. In § 558.45, by removing paragraphs (b), (c), (d), and (e), by redesignating existing paragraph (f) as paragraph (b), and by revising paragraph (a), to read as follows:

**§ 558.45 Ammonium chloride, feed grade.**

(a) *Approvals.* Type A medicated articles: 99 percent to 011462 in § 510.600(c) of this chapter.

* * * * *

31. In § 558.55, by revising paragraph (a), by removing paragraph (b), by redesignating existing paragraph (c) as paragraph (b) and revising it, by redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively, to read as follows:

**§ 558.55 Amprolium.**

(a) *Approvals.* Type A medicated articles: 25 percent to 000006 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

32. In § 558.58, by removing paragraph (b), by revising paragraph (a), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by revising redesignated paragraph (b) and the introductory text of redesignated paragraph (d), to read as follows:

**§ 558.58 Amprolium and ethopabate.**

(a) *Approvals.* Type A medicated articles: (1) 25 percent amprolium and 0.8 percent ethopabate; 25 percent amprolium and 8 percent ethopabate; 5 percent amprolium and 0.16 percent ethopabate; 5 percent amprolium and 1.6 percent ethopabate; to 000006.

(2) 0.15 percent amprolium and 0.004 percent ethopabate and 0.5 gram per pound bacitracin (as bacitracin methylene disalicylate) to 047019 in § 510.600(c) of this chapter.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

(d) *Conditions of use.* It is used for chickens as follows:

* * * * *

33. In § 558.60, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, by revising paragraph (a) and the introductory text of redesignated paragraph (c)(1), to read as follows:

**§ 558.60 Arsanilate sodium.**

(a) *Appprovals.* Type A medicated articles: 20, 50, or 100 percent to 043731 in § 510.600(c) of this chapter.

* * * * *

(c) *Conditions of use.* (1) It is used for chickens and turkeys as follows:

* * * * *

34. In § 558.62, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a) and the introductory text of redesignated paragraph (c)(1), to read as follows:

**§ 558.62 Arsanilic acid.**

(a) *Approvals.* Type A medicated articles: 20, 50, or 100 percent to 043731 in § 510.600(c) of this chapter.

* * * * *

(c) *Conditions of use.* (1) It is used for chickens and turkeys as follows:

* * * * *

35. In § 558.76, by removing paragraph (b), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (b) and the introductory text of redesignated paragraph (d)(1), to read as follows:

**§ 558.76 Bacitracin methylene disalicylate.**

(a) *Approvals.* Type A medicated articles: 25, 40, or 50 percent to 046573 in § 510.600(c) of this chapter.

(b) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

* * * * *

(d) *Conditions of use.* It is used as follows:

* * * * *

36. In § 558.78, by removing paragraph (b), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (b) and the introductory text of redesignated paragraph (d)(1), to read as follows:

**§ 558.78 Bacitracin zinc.**

(a) *Approvals.* Type A medicated articles: (1) 50 grams per pound to 046573 in § 510.600(c) of this chapter for use as in paragraph (d)(1)(i) and (ii) of this section.

(2) 10, 25, 40, and 50 grams per pound to 012769 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(3) 5 and 50 grams per pound to 000010 in § 510.600(c) of this chapter for use in chickens as in paragraph (d)(1)(i) of this section.

(b) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

* * * * *

(d) *Conditions of use.* (1) It is used as follows:

* * * * *

37. In § 558.95, by removing paragraphs (b), (c), and (d), by redesignating existing paragraph (e) as paragraph (b), and by revising paragraph (a) and the introductory text of redesignated paragraph (b)(1) and (2), to read as follows:

**§ 558.95 Bambermycins.**

(a) *Approvals.* Type A medicated articles: (1) 2 and 10 grams of activity per pound to 012799 in § 510.600(c) of this chapter for use as in paragraph (b)(1), (2)(i) and (ii), and (3) of this section.

(2) 0.4 gram of activity per pound to 012799 and 020275 for use as in paragraph (b)(2) of this section.

(3) 0.4 and 2 grams of activity per pound to 011490 in § 510.600(c) of this chapter for use as in paragraph (b)(2) of this section.

(4) 0.4 and 2 grams of activity per pound for use as in paragraph (b)(2) of this section and 2 grams of activity per pound for use as in paragraph (b)(3) of this section to 016968, 017274, and 017790 in § 510.600(c) of this chapter.

(5) 0.08 gram of activity per pound for use as in paragraph (b)(2) of this section to 034139 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Broiler chicken.* It is used as follows:

* * * * *

(2) *Growing-finished swine.* It is used as follows:

* * * * *

38. In § 558.105, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (b) and the introductory text of redesignated paragraph (d), to read as follows:

**§ 558.105 Buquinolate.**

(a) *Approvals.* Type A medicated articles: 16.5 and 22 percent to 000149 in § 510.600(c) of this chapter.

(b) *Special considerations.* Do not use in Type B or Tpye C medicated feeds containing bentonite.

* * * * *

(d) *Conditions of use.* It is used as follows:

* * * * *

39. In § 558.115, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (c) and the introductory text of redesignated paragraph (d), to read as follows:

**§ 558.115 Carbadox.**

(a) *Approvals.* Type A medicated articles: 2.2. percent (10 grams per pound) to 000069 in § 510.600(c) of this chapter.

* * * * *

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used for swine as follows:

* * * * *

40. In § 558.120, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a) and the introductory text of redesignated paragraph (c)(1), to read as follows:

**§ 558.120 Carbarsone (not U.S.P.).**

(a) *Approvals.* Type A medicated articles: (1) 37.5 percent to 011794 in § 510.600(c) of this chapter.

(2) 25 percent carbarsone and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 011794 in § 510.600(c) of this chapter.

* * * * *

(c) *Conditions of use.* It is used for turkeys as follows:

* * * * *

41. In § 558.128, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

* * * * *

**§ 558.128 Chlortetracycline.**

(a) *Approvals.* Type A medicated articles: 10 and 50 grams per pound chlortetracycline to 010042 in § 510.600(c) of this chapter; 35 grams chlortetracycline with 7.7 percent (35 grams) sulfamethazine to 010042 in § 510.600(c) of this chapter.

* * * * *

42. In § 558.145, by removing paragraphs (c) and (d), by redesignating existing paragraphs (e) and (f) as paragraphs (c) and (d), respectively, and by revising paragraphs (a) and (b), to read as follows:

**§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.**

(a) *Approvals.* Type A medicated articles: (1) 20 grams of chlortetracycline per pound, 4.4 percent (20 grams) of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound to 000069 and 010042 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and penicillin procaine equivalent in activity to 20 grams of penicillin per pound to 010042 in § 510.600(c) of this chapter.

(b) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(3) Type C medicated feed contains in each ton, 100 grams of chlortetracycline, 50 grams of penicillin as procaine penicillin, and 100 grams of sulfamethazine.

* * * * *

43. In § 558.155, by removing paragraphs (c) and (d), by redesignating existing paragraphs (e) and (f) as paragraphs (c) and (d), respectively, and by revising paragraphs (a) and (b) and the introductory text of redesignated paragraph (d), to read as follows:

**§ 558.155 Chlortetracycline, procaine penicillin, and sulfathiazole.**

(a) Approvals. Type A medicated articles: (1) 20 grams of chlortetracycline hydrochloride, 4.4 percent (20 grams) sulfathiazole, and procaine penicillin equivalent to 10 grams of penicillin per pound to 052313 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline hydrochloride, 8.8 percent (40 grams) sulfathiazole and procaine penicillin equivalent in activity to 20 grams of penicillin per pound to 052313 in § 510.600(c) of this chapter.

(b) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

* * * * *

(d) *Conditions of use.* It is used for swine as follows:

* * * * *

44. In § 558.175, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), as paragraphs (b) and (c) respectively, and by revising paragraph (a), to read as follows:

**§ 558.175 Clopidol.**

(a) Approvals. Type A medicated articles: (1) 25 percent to 025700 in § 510.600(c) of this chapter.

(2) 25 percent of clopidol, 10 percent of roxarsone; and 4, 10, 15, or 25 grams of bacitracin methylene disalicylate per pound to 025700 in § 510.600(c) of this chapter.

* * * * *

45. In § 558.185, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (b), to read as follows:

**§ 558.185 Coumaphos.**

(a) *Approvals.* Type A medicated articles: (1) 1.12, 2.0, 11.2, and 50 percent to 000859 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) 1.12 and 11.2 percent to 017800 in § 510.600(c) of this chapter for use as in paragraph (d)(1)(ii) of this section.

(b) *Special considerations.* Adequate directions and warnings for use must be given and shall include a statement that coumaphos is a cholinesterase inhibitor and that animals being treated with coumaphos should not be exposed during or within a few days before or after treatment to any other cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

* * * * *

46. In § 558.195, by removing paragraphs (b), (c), and (d), by redesignating existing paragraphs (e), (f), and (g) as paragraphs (b), (c), and (d), respectively, and by revisions paragraph (a), to read as follows:

**§ 558.195 Decoquinate**

(a) *Approvals.* Type A medicated articles: 6 percent to 011801 in § 510.600(c) of this chapter.

* * * * *

47. In § 558.205, by removing paragraphs (b) and (c), by redesignating exisitng paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a), to read as follows:

**§ 558.205 Dichlorvos.**

(a) *Approvals.* Type A medicated articles: 3.1 and 9.6 percent to 052313 in § 510.600(c) of this chapter.

* * * * *

48. In § 558.240, by removing paragraphs (b) and (c), by redesignating exisitng paragraphs (d) and (e) as paragraphs (b) and (c) respectively, and by adding paragraph (a), to read as follows:

**§ 558.240 Dimetridazole.**

(a) *Approvals.* Type A medicated articles: 30 percent to 017210 in § 510.600(c) of this chapter.

* * * * *

49. In § 558.248, by removing paragraph (b) by redesignating exisitng paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), and by revising paragraph (a), and redesignated paragraph (b) and the introductory text of redesignated paragraph (d)(1), to read as follows:

**§ 558.248 Erythromycin thiocyanate.**

(a) *Approvals.* Type A medicated articles: (1) 2.2 percent to 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) 5 and 10 percent to 050604 in § 510.600(c) of this chapter for use as in paragraph (d)(1) (i) and (iii) of this section.

(b) *Special considerations.* The levels of antibiotic are expressed in terms of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromcin master standard.

* * * * *

(d) *Condition of use.* (1) It is used as follows:

* * * * *

50. In § 558.254, by removing paragraph (b), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by adding paragraph (a), to read as follows:

**§ 558.254 Famphur.**

(a) *Approvals.* Type A medicated articles: 13.2 and 33.3 percent to 010042 in § 510.600(c) of this chapter.

* * * * *

51. In § 558.258, by removing paragraph (b), by redesignating exisitng paragraphs (c) and (d) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.258 Fenbendazole.**

(a) *Approvals.* Type A medicated articles: 4 percent (18.1 grams per pound) fenbendazole and 20 percent (90.7 grams per pound) fenbendazole to 012799 in § 510.600(c) of this chapter.

* * * * *

52. In § 558.262, by removing paragraphs (b) and (c), by redesignating exisitng paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by adding paragraph (a), to read as follows:

**§ 558.262 Furazolidone.**

(a) *Approvals.* Type A medicated articles: 10, 50, and 100 grams per pound to 000007 in 011801 in § 510.600(c) of this chapter.

* * * * *

53. In § 558.265, by removing paragraphs (b) and (c), by redesignating exisitng paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.265 Halofuginone hydrobromide.**

(a) *Approvals.* Type A medicated articles: 6 grams per kilogram (2.72 grams per pound) to 012799 in § 510.600(c) of this chapter.

* * * * *

54. In § 558.274, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.274 Hygromycin B.**

(a) *Approvals.* (1) Type A medicated articles: 2.4 and 8 grams per pound to 000986 in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(2) 2.4 grams per pound to 011490, 016968, 018083, and 043733 in § 510.600(c) of this chapter for use in swine feed as in paragraph (c)(1)(ii) of this section.

(3) 1.2 grams per pound to 016968 in § 510.600(c) of this chapter for use in swine as in paragraph (c)(1)(ii) of this section.

(4) 0.6 gram per pound to 016968, 017434, 017473, 017519, 017790, 018083, 020275, 022422, 026948, 043733, 050568, and 050639 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

(5) 0.48 and 2.4 grams per pound to 026186 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

(6) 0.8 and 1.6 grams per pound to 043734 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section.

(7) 2.4 grams per pound to 011790 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

* * * * *

55. In § 558.305, by removing paragraphs (b), (c), and (e), by redesignating existing paragraphs (d) and (f) as paragraphs (b) and (c), respectively, and by revising paragraph (a) and the introductory text of redesignated paragraph (c), to read as follows:

**§ 558.305 Ipronidazole.**

(a) *Approvals.* Type A medicated articles: 12.5 percent to 000004 in § 510.600(c) of this chapter.

* * * * *

(c) *Conditions of use.* It is used for turkeys as follows:

* * * * *

56. In § 558.311, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a), to read as follows:

**§ 558.311 Lasalocid.**

(a) *Approvals.* Type A medicated articles: (1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity granted to 000004 in § 510.600(c) of this chapter for use as in paragraph (d) (1), (2), (3), and (4) of this section.

(2) 15 percent activity to 000007 as provded by 000004 in § 510.600(c) of this chapter for use as in paragraph (d)(5) of this section.

(3) 15, 20, 33.1, and 50 percent activity to 000004 in § 510.600(c) of this chapter for use in feed for cattle as provided in paragraph (d) (6) and (7) of this section. Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle feed only.

* * * * *

57. In § 558.315, by removing paragraphs (b), (c), (d), and (f), by redesignating existing paragraphs (e) and (g) as paragraphs (b) and (c), respectively, and by revising paragraph (a) and the introductory text of redesignated paragraph (c), to read as follows:

**§ 558.315 Levamisole hydrochloride (equivalent).**

(a) *Approvals.* Type A medicated articles: 227 grams per pound to 043781 in § 510.600(c) of this chapter.

* * * * *

(c) *Conditions of use.* It is used in Type C medicated feed as follows:

* * * * *

58. In § 558.325, by removing paragraphs (b), (c), and (e), by redesignating existing paragraphs (d) and (f) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.325 Lincomycin.**

(a) *Approvals.* Type A medicated articles: (1) 4 grams per pound to:

(i) 000009 in § 510.600(c) of this chapter for use as in paragraph (c)(1) and (3) of this section.

(ii) 034139 in § 510.600(c) of this chapter for use as in paragraph (c)(2) of this section.

(2) 20 grams per pound to 000009 in § 510.600(c) of this chapter for use as in paragraph (c)(1), (2), and (3) of this section.

(3) 50 grams per pound to 000009 in § 510.600(c) of this chapter for use as in paragraph (c)(1) and (2) of this section.

(4) 8, 10, and 20 grams per pound to 011490 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(5) 8 and 20 grams per pound to 043733, 050639, and 051359 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(6) 4, 8, 10, and 20 grams per pound to 018083 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(7) [Reserved]

(8) 4, 5, 8, 10, and 20 grams per pound to 016968 for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(9) 4 and 20 grams per pound to 047427 in § 510.600(c) of this chapter for use as in paragraph (c)(2) of this section.

(10) 4, 8, and 20 grams per pound to 017274 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(11) 5 and 10 grams per pound to 012286 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(12) 20 grams per pound to 020275 in § 510.600 of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(13) 2.5 and 8 grams per pound to 017800 in § 510.600(c) of this chapter for use as in paragraph (c)(2) of this section.

(14) 4 and 20 grams per pound to 024174 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(i), (ii), and (iii) of this section.

(15) 8 and 20 grams per pound to 017790 in § 510.600(c) of this chapter for use as in paragraph (c)(2) of this section.

* * * * *

59. In § 558.342, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.342 Melengestrol acetate.**

(a) *Approvals.* Dry Type A medicated articles: 100 or 200 milligrams per pound or liquid premix containing 500 milligrams per pound to 000009 in § 510.600(c) of this chapter.

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60. In § 558.355, by removing and reserving paragraphs (a) and (d)(3) and (4), by revising the introductory text of paragraph (b), and by revising paragraph (c), to read as follows:

**§ 558.355 Monensin.**

(a) [Reserved]

(b) *Approvals.* Approvals for Type A medicated articles containing the specified levels of monensin activity granted to firms identified by sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

* * * * *

(c) *Assay limits.* Liquid feed supplements contain 80 to 120 percent of the labeled amount of monensin activity.

* * * * *

61. In § 558.360, by removing paragraph (b), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (c)(1), to read as follows:

**§ 558.360 Morantel tartrate.**

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 000069 in § 510.600(c) of this chapter.

* * * * *

(c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

62. In § 558.365, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (c), to read as follows:

**§ 558.365 Nequinate.**

(a) *Approvals.* Type A medicated articles: 4 percent to 017800 in § 510.600(c) of this chapter.

* * * * *

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

63. In § 558.366, by removing paragraphs (b) and (d), by redesignating existing paragraphs (c) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.366 Nicarbazin.**

(a) *Approvals.* Type A medicated articles: 25 percent to 000006 and 000986 in § 510.600(c) of this chapter.

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64. In § 558.367, by removing paragraph (b), by redesignating existing paragraph (c) as paragraph (b), and by revising paragraph (a), to read as follows:

**§ 558.367 Niclosamide.**

(a) *Approvals.* Type A medicated articles: 66 percent to 000859 in § 510.600(c) of this chapter.

* * * * *

65. In § 558.369, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a), to read as follows:

**§ 558.369 Nitarsone.**

(a) *Approvals.* Type A medicated articles: 50 percent to 017210 in § 510.600(c) of this chapter.

* * * * *

66. In § 558.370, by removing paragraphs (b) and (c), by redesignating existing paragraph (d) as paragraph (b), and by revising paragraph (a), to read as follows:

**§ 558.370 Nitrofurazone.**

(a) *Approvals.* Type A medicated articles: 50 grams per pound to 000007 and 011801 in § 510.600(c) of this chapter.

* * * * *

67. In § 558.376, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by adding paragraph (a), to read as follows:

**§ 558.376 Nitromide and sulfanitran.**

(a) *Approvals.* Type A medicated articles: 25 percent nitromide, 30 percent sulfanitran, with or without 5 percent roxarsone to 017210 in § 510.600(c) of this chapter.

* * * * *

68. In § 558.415, by removing paragraphs (b), (c), and (d), by redesignating existing paragraphs (e) and (f) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.415 Novobiocin.**

(a) *Approvals.* Type A medicated articles: 25 grams of activity per pound to 000009 in § 510.600(c) of this chapter.

* * * * *

69. In § 558.430, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by adding paragraph (a), to read as follows:

**§ 558.430 Nystatin.**

(a) *Approvals.* Type A medicated articles: 20 grams of activity per pound to 000003 in § 510.600(c) of this chapter.

* * * * *

70. In § 558.435, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (c), to read as follows:

**§ 558.435 Oleandomycin.**

(a) *Approvals.* Type A medicated articles: 5 grams of activity per pound to 000069 in § 510.600(c) of this chapter.

* * * * *

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing oleandomycin.

* * * * *

71. In § 558.450, by removing paragraph (b), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (b), to read as follows:

**§ 558.450 Oxytetracycline.**

(a) *Approvals.* Type A medicated articles: (1) 10 and 50 grams per pound to 000069 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) 100 grams per pound to 000069 in § 510.600(c) of this chapter for use as in paragraph (d)(1), table 1, item (v) of this section.

(b) *Special considerations.* The amount of oxytetracycline is expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

* * * * *

72. In § 558.460, by removing paragraphs (b), (c), and (d), by redesignating existing paragraphs (e) and (f) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.460 Penicillin.**

(a) *Specifications.* As penicillin procaine G or feed grade penicillin procaine.

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73. In § 558.464, by removing paragraph (b), by redesignating existing paragraph (c) as paragraph (b), and by revising paragraph (a), to read as follows:

**§ 558.464 Poloxalene.**

(a) *Approvals.* (1) Dry Type A medicated articles: 53 percent to 000007 in § 510.600(c) of this chapter.

(2) Liquid Type A medicated articles: 99.5 percent to 000007 in § 510.600(c) of this chapter.

* * * * *

74. In § 558.465, by removing paragraphs (b) and (c), by redesignating existing paragraph (d) as paragraph (b), and by revising the section heading and paragraph (a), to read as follows:

**§ 558.465 Poloxalene liquid Type C medicated feed article.**

(a) *Approvals.* Type A medicated articles: 99.5 percent to 000007 in § 510.600(c) of this chapter.

* * * * *

75. In § 558.485, by removing and reserving paragraph (b), by revising the introductory text of paragraph (a), and

by revising paragraph (d), to read as follows:

**§ 558.485 Pyrantel tartrate.**

(a) *Approvals.* Type A medicated articles containing pyrantel tartrate to firms identified by drug labeler codes in § 510.600(c) of this chapter for the specific usage indicated in paragraph (e) of this section:

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(b) [Reserved]

* * * * *

(d) *Special considerations.* (1) Consult veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or Type C medicated feeds containing bentonite.

* * * * *

76. In § 558.515, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and the second sentence in redesignated paragraph (b), to read as follows:

**§ 558.515 Robenidine hydrochloride.**

(a) *Approvals.* Type A medicated articles: 30 grams per pound to 010042 in § 510.600(c) of this chapter.

(b) * * * Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

77. In § 558.525, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a), to read as follows:

**§ 558.525 Ronnel.**

(a) *Approvals.* Type A medicated articles: (1) 18 and 40 percent to 025700 in § 510.600(c) of this chapter.

(2) 5.5 percent in mineral mix to 021930 in § 510.600(c) of this chapter.

* * * * *

78. In § 558.530, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a), to read as follows:

**§ 558.530 Roxarsone.**

(a) *Approvals.* Type A medicated articles: (1) 10, 20, and 50 percent to 011801 in § 510.600(c) of this chapter for use in making chicken and turkey feeds.

(2) 10, 20, 50, and 80 percent to 017210 in § 510.600(c) of this chapter for use in making chicken, turkey, and swine feeds.

* * * * *

79. In § 558.550, by removing paragraph (b), by redesignating existing paragraph (c) as paragraph (b), and by revising paragraph (a), to read as follows:

**§ 558.550 Salinomycin.**

(a) *Approvals.* Type A medicated articles: 30 grams of activity from salinomycin sodium biomass to 000031 in § 510.600(c) of this chapter.

* * * * *

80. In § 558.575, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.575 Sulfadimethoxine, ormetoprim.**

(a) *Approvals.* Type A medicated articles: 25 percent of sulfadimethoxine and 15 percent of ormetoprim and 25 percent of sulfadimethoxine and 5 percent of ormetoprim to 000004 in § 510.600(c) of this chapter.

* * * * *

81. In § 558.579, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c) respectively, and by revising paragraph (a), to read as follows:

**§ 558.579 Sulfaethoxypyridazine.**

(a) *Approvals.* Type A medicated articles: 5.5 percent for swine, and 5.5 and 11 percent for cattle to 010042 in § 510.600(c) of this chapter.

* * * * *

82. In § 558.582, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.582 Sulfamerazine.**

(a) *Approvals.* Type A medicated articles: 99 percent to 010042 in § 510.600(c) of this chapter.

* * * * *

83. In § 558.586, by removing and reserving paragraphs (b) and (c) and by revising the section heading and adding paragraph (a), to read as follows:

**§ 558.586 Sulfaquinoxoline.**

(a) *Approvals.* Type A medicated articles: 40 percent to 000006 in § 510.600(c) of this chapter.

(b)–(c) [Reserved]

* * * * *

84. In § 558.615, by removing paragraph (b), by redesignating existing paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively, and by revising paragraph (a) and redesignated paragraph (b), to read as follows:

**§ 558.615 Thiabendazole.**

(a) *Approvals.* Dry Type A medicated articles: 22, 44.1, 66.1, and 88.2 percent to 000006 in § 510.600(c) of this chapter. The 66.1 percent Type A is solely for the manufacture of cane molasses liquid Type C medicated feed article which is mixed in dry feeds. The 88.2 percent Type A is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) *Special considerations.* Do not use in Type B or Type C medicated foods containing bentonite.

* * * * *

85. In § 558.625, by removing and reserving paragraphs (c) and (d) and by revising the introductory text of paragraph (b), to read as follows:

**§ 558.625 Tylosin.**

* * * * *

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

* * * * *

(c)–(d)–[Reserved]

* * * * *

86. In § 558.630, by removing and reserving paragraphs (a), (c), and (d), and by revising the introductory text of paragraph (b), to read as follows:

**§ 558.630 Tylosin and sulfamethazine.**

(a) [Reserved]

(b) *Approvals.* Type A medicated article levels, a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section.

* * * * *

(c)–(d) [Reserved]

* * * * *

87. In § 558.635, by removing and reserving paragraphs (a), (c), and (e) (3) and (4), and by revising paragraph (b), to read as follows:

**§ 558.635 Virginiamycin.**

(a) [Reserved]

(b) *Approvals.* Type A medicated articles. (1) 1.1 percent activity (5 grams per pound), 2.2 percent activity (10 grams per pound), 4.4 percent activity (20 grams per pound), 11 percent activity (50 grams per pound), and 50 percent activity (227 grams per pound) to 000007 in § 510.600(c) of this chapter.

(2) 2.2 percent activity (10 grams per pound) to 011490, 016968, 017274, 017790, and 047427 in § 510.600(c) of this chapter

for use as in paragraph (f)(1) (iv) and (v) of this section.

(c) [Reserved]

* * * * *

(e) * * *

(3)–(4) [Reserved]

* * * * *

In § 558.680, by removing paragraphs (b) and (c), by redesignating existing paragraphs (d) and (e) as paragraphs (b) and (c), respectively, and by revising paragraph (a), to read as follows:

**§ 558.680 Zoalene.**

(a) *Approvals.* Type A medicated articles: 25 percent to 017210 in § 510.600(c) of this chapter.

* * * * *

Dated: January 28, 1986.

**Frank E. Young,**

*Commissioner of Food and Drugs*

**Otis R. Bowen,**

*Secretary of Health and Human Services.*

[FR Doc. 86–4316 Filed 2–28–86; 8:45 am]

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March 3, 1986

Part V

# Department of Health and Human Services

Food and Drug Administration

21 CFR Part 884

Obstetrical-Gynecological Devices; Transabdominal Amnioscope (Fetoscope) and Accessories; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 884**

**[Docket No. 85N-0494]**

## Obstetrical-Gynecological Devices; Premarket Approval of the Transabdominal Amnioscope (Fetoscope) and Accessories

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule; opportunity to request change in classification.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the transabdominal amnioscope (fetoscope) and accessories, a medical device. The agency is also summarizing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements, and (2) the benefits to the public from the use of the device. In addition, FDA is announcing an opportunity for interested persons to request the agency to change the classification of the device based on new information.

**DATES:** Written comments by May 2, 1986; requests for a change in classification by March 18, 1986.

**ADDRESS:** Written comments or requests for a change in classification are to be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Raju G. Kammula, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

**SUPPLEMENTARY INFORMATION:** Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: class I, general controls; class II, performance standards; and class III, premarket approval. As a general rule, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), and devices marketed on or after that date that are substantially equivalent to such devices, have been, or are being, classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as "preamendments devices."

Sections 501(f), 513, 515(b) of the act (21 U.S.C. 351(f), 360c, and 360e(b)), taken together, establish as a general requirement that a preamendments device that FDA has classified into class III is subject, in accordance with section 515, to premarket approval. (As an alternative procedure for premarket approval, section 515(f) of the act provides for the development of a PDP, the last stage of which is for FDA to declare that a PDP has been completed.) A preamendments class III device may be commercially distributed without a filed PMA or a notice of completion of a PDP until 90 days after FDA's promulgation of a final rule requiring premarket approval for the device. Also, such a device is exempt from the investigational device exemption (IDE) regulations (21 CFR Part 812) until the date stipulated by FDA in the final rule requiring premarket approval for that device. A device that was not in commercial distribution before May 28, 1976, or that has not been found by FDA to be substantially equivalent to such a device, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

Section 515(b)(2)(A) of the act provides that a proceeding for the promulgation of a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed rule and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice either denying the request or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, promulgate a final rule to require premarket approval, or publish a notice terminating the proceeding. If the proceeding is terminated, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f) of the act requires that a PMA or a notice of completion of a PDP for the device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP has not been filed, and there is not any IDE in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334). Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333).

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that "the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigation necessary to support an application for premarket approval." H. Rept. 94-853, 94th Cong., 2d Sess. 42 (1976).

### Classification of the Transabdominal Amnioscope (Fetoscope) and Accessories

In the **Federal Register** of February 26, 1980 (45 FR 12688), FDA issued a final rule (21 CFR 884.1600) classifying the transabdominal amnioscope (also known as the fetoscope) and accessories into class III. The preamble to the proposal to classify the device (44 FR

19907; April 3, 1979) included the recommendation of the Obstetrics-Gynecology Devices Panel (formerly) the Obstetrical and Gynecological Device Classification Panel) (the Panel), an FDA advisory committee, regarding the classification of the device. The Panel's recommendation included a summary of the reasons the device should be subject to premarket approval and identified certain risks to health presented by the device. The Panel also recommended under section 513(c)(2)(A) of the act that a high priority for the application of section 515 of the act be asigned to the transabdominal amnioscope and accessories. The preamble to the final rule classifying the device advised that the earliest date by which a PMA for the device (or a notice of completion of a PDP) could be required was September 30, 1982, or 90 days after promulgation of a rule requiring premarket approval for the device, whichever occurred later.

In the **Federal Register** of September 6, 1983 (48 FR 40272), FDA published a notice of intent to initiate proceedings to require premarket approval of 13 preamendments class III devices assigned a high priority by FDA for the application of premarket approval requirements. Among other things, the notice describes the factors FDA takes into account in establishing priorities for initiating proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's or declared completed PDP's. Using these factors, FDA has determined that the transabdominal amnioscope and accessories identified in § 884.1600(a) has a high priority for initiating a proceeding to require premarket approval. Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the transabdominal amnioscope and accessories have an approved PMA or a PDP that has been declared completed.

### Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is now proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for the transabdominal amnioscope and accessories within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was in commercial distribution before May 28, 1976, or whose device has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the transabdominal amnioscope and accessories during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days, of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period for a PMA unless the agency finds that "* * * the continued availability of the device is necessary for the public health."

FDA intends that, under § 812.2(d), the preamble to any final rule based on this proposal will stipulate that, as of the date on which a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c) (1) and (2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any transabdominal amnioscope and accessories: (1) That is not legally on the market on or before that date or (2) that is legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or a notice of completion of a PDP for the transabdominal amnioscope and accessories is not filed with FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device will be required to cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period to avoid interrupting investigations.

### Description of Device

A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. The generic type of device may include the following accessories: Trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

The proposed rule to require premarket approval of the tansabdominal amnioscope and accessories applies to transabdominal amnioscope (fetoscope) products and accessories for use with the products that were being commercially distributed before May 28, 1976, and to devices introduced into commercial distribution since that date which have been found to be substantially equivalent to such transabdominal amnioscopes and accessories.

### Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the Act, FDA is publishing its proposed findings regarding (1) the degree of risk of illness or injury designed to be eliminated or reduced by requiring the transabdominal amnioscope and accessories to have an approved PMA or a declared completed PDP and (2) the benefits to the public from the use of the device.

*Degree of Risk*

In 1979, the Panel considered the appropriate classification of the transabdominal amnioscope and accessories. After reviewing all available literature on the transabdominal amnioscope, the Panel recommended that the device and its accessories be classified into class III (44 FR 19907; April 3, 1979). The Panel based its recommendation, in part, on its conclusion that satisfactory performance of the device has never been demonstrated, that available information is insufficient to establish a standard to provide assurance of the device's safety and effectiveness, and that clinical experience with the device is too limited to establish that general controls would assure its safe and effective use.

The Panel identified several risks to health associated with the use of the device: Tissue burns, infection, electrical shock, trauma, adverse tissue reaction, spontaneous abortion, and premature delivery. In addition, FDA reviewed data and information describing the application of the transabdominal amnioscope to examine the fetus visually and to collect tissue samplings. Based on FDA's review of these data and information, some of which were not available at the time of the Panel meeting, the agency concluded that the device presents a potential unreasonable risk of illness or injury due to risks associated with its use, including the reported frequency of diagnostic error, failure of sample acquisition, and fetal loss. For these reasons, FDA found that the value of diagnostic information on fetal status obtained with the use of the device may

not outweigh the fetal risk presented by the device. Accordingly, FDA determined that the transabdominal amnioscope and accessories should be subject to premarket approval.

Since the time of classification of the device, FDA has evaluated the risks then determined to be associated with the use of the transabdominal amnioscope and accessories. Based on that evaluation, FDA believes that with the development of fiber optics and remote light source, current models of the device no longer present the risks of tissue burns and electrical shock. FDA believes that the following are significant risks which continue to be associated with the use of transabdominal amnioscope (fetoscope) products and the accessories used with these products:

*Spontaneous abortion.* Spontaneous abortion is one of the most serious risks of fetoscopy. The incidence of spontaneous abortion following fetoscopy was recently reported to be 6.8 percent for fetal blood sampling, 7.9 percent for fetal visualization, and 16 percent for fetal skin biopsy (Ref. 19). Moreover, the incidence of spontaneous abortion has been found to be higher in patients for whom a followup second fetoscopy procedure was necessary whether the followup procedure was conducted on the same day as the first procedure or later (Refs. 2 and 23).

*Premature delivery.* The incidence of premature delivery of the fetus following fetoscopy for sampling of fetal blood range between 5.3 percent and 14.8 percent (Refs. 2 and 23). According to Antsaklis (Ref. 2) and Ward and Modell (Ref. 23), many factors contribute to premature delivery of the fetus, but the average incidence of 10 percent premature delivery following fetoscopy was much higher than the estimated 1.5 percent expected in a normal group of patients. Therefore, these authors conclude that fetoscopy has to be considered an additional hazard contributing to premature delivery. These authors also report that the incidence of premature delivery following fetal visualization with transabdominal amnioscope devices is much higher than that following fetal blood sampling with the devices, probably because of the additional manipulation of the fetoscope required for visually identifying developmental abnormalities.

*Fetal and maternal injuries.* Direct damage to the fetus and to the mother has been reported following fetoscopy (Refs. 2, 3, 8, 12, 14, and 17). Hobbins and Mahoney (Ref. 8) reported fetal bleeding both into amniotic fluid and maternal circulation. Rodeck and Nicolaides (Ref. 16) reported a rise in maternal serum alpha-fetoprotein concentration indicating feto-maternal hemorrhage as a result of punctured chorionic plate vessels during fetoscopy. Feto-maternal hemorrhage in Rh-negative mothers is a potential complication due to isoimmunization (Ref. 16). In addition, it has been suggested that the bright light source might damage the fetal retina during fetoscopy (Ref. 16).

Amnionitis and leakage of amniotic fluid as a result of trauma are the two significant maternal complications following fetoscopy (Refs. 3 and 13). The incidence of amnionitis has been reported to be about 1 percent and leakage of amniotic fluid to be 5 percent (Refs. 3 and 13). According to Antsaklis (Ref. 2) and Ward and Modell (Ref. 23), trauma either to the fetus or to the uterus of the mother is the main cause of spontaneous abortion following fetoscopy. Early studies indicate, however, that the use of small diameter fetoscopes (1.7 to 3.1 millimeters) may reduce these risks (Ref. 3).

*Infection.* Rocker and Laurence report that infection is a significant hazard both to the fetus and to the mother (Refs. 2 and 14). The incidence of fetal infection following fetoscopy is about 1 percent. These authors considered the observed fetal infection, in some cases, to be the direct cause of fetal death. During fetoscopy procedures, antibiotics are routinely administered to the patients (Ref. 2) to minimize maternal infection. Fetal infection can be so serious, however, that it causes septic abortion (infected miscarriage) followed in some cases by blood poisoning (septicemia) which can lead to death.

*Adverse tissue reaction.* Materials or substances used to manufacture transabdominal amnioscope (fetoscope) devices and the accessories used with these devices could cause systemic or local tissue reaction, when the devices contact the maternal or fetal tissues. Because the devices used for fetoscopy come in direct contract with very sensitive fetal and maternal tissues, biocompatibility of the device materials is essential to provide reasonable assurance of the safety of the device.

*Benefits of the Device*

Fetoscopy is performed to visualize the fetus or to sample fetal tissues for the diagnosis of fetal conditions that are difficult or impossible to diagnose with ultrasonography or amniocentesis (Refs. 5, 13, 14, 16, 18, 20, and 21). Visual examination of the fetus has successfully diagnosed craniofacial defects, limb defects, and neural tube defects (Ref. 15). Several skin diseases have been diagnosed by fetal skin biopsy using the transabdominal amnioscope and accessories (Ref. 4). Other prenatal diagnoses of specific conditions that have been accomplished with fetoscopy include hemoglobinopathies (Refs. 1 and 22), hemophilias (Refs. 7 and 9), white blood cell and platelet disorders (Ref. 10), red cell typing (Ref. 11), and several enzyme deficiencies (Ref. 3). Diagnosis of a normal healthy fetus by fetoscopy provides the benefit of reassurance to parents who are at high risk of a pregnancy with genetic or developmental abnormalities such as the defects and conditions discussed above.

In summary, fetoscopy offers a valuable tool in the prenatal diagnosis of conditions that cannot be diagnosed by ultrasonography or amniocentesis, though the procedure is not without certain attendant risks as well as the possibility of failure to provide diagnostic information. FDA believes, however, that fetoscopy using the transabdominal amnioscope and accessories can be beneficial in prenatal diagnosis for genetic diseases and developmental abnormalities in high-risk patients.

*Discussion of Risks and Benefits*

FDA classified the transabdominal amnioscope and accessories into class III because insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has weighed the probable risks and benefits to the public from use of the transabdominal amnioscope and accessories and believes that the studies discussed above present evidence of significant risks associated with the use of the device. These risks must be addressed by manufacturers of the device.

Fetal infection is a serious complication associated with the fetoscopy procedure. The incidence of fetal infection associated with use of the transabdominal amnioscope and accessories leading to spontaneous abortion has been reported (Ref. 14). FDA believes, therefore, that the rate, type, severity, and outcome of these infections should be clearly documented for any transabdominal amnioscope and accessories for which premarket approval is sought.

Fetal trauma leading to fetal deformities and fetal loss has been reported following fetoscopy (Refs. 2, 3,

6, 8, 12, 14, and 17). FDA believes that the difference in rate, type, severity, and outcome of fetal trauma following fetal blood or tissue sampling and following fetal visualization should be clearly documented for each device.

Leakage of amniotic fluid and amnionitis are severe maternal complications frequently caused by the fetoscopy procedure (Refs. 3 and 13). Feto-maternal hemorrhage as a result of punctured chorionic plate vessels has also been reported (Ref. 16). FDA believes that the rate, type, severity, and outcome of all the maternal complications associated with the use of each transabdominal amnioscope and accessories should be clearly documented.

Spontaneous abortion and premature delivery have been reported following fetoscopy (Refs. 2, 14, and 23). FDA believes that the incidence of spontaneous abortion and premature delivery for each indication (fetal blood or tissue sampling and fetal visualizaton) should be clearly established for each device.

Although the transabdominal amnioscope and accessories may provide prenatal diagnostic data that are unavailable with other methods, fetal blood sampling and fetal visualization by fetoscopy have often failed to provide the necessary diagnostic data. Fetal blood obtained by the procedure may be contaminated with amniotic fluid. Fetal visualization has been reported as failing in 13 percent of the attempted cases (Ref. 3). For these reasons, FDA believes that the diagnostic effectiveness of fetoscopy must be documented in terms of effective fetal blood or tissue sampling and fetal examination.

Because the transabdominal amnioscope and accessories come in contact with very sensitive fetal and maternal tissues, FDA believes that the safety of all the materials used in the device that come in contact with tissues must be established by adequate biocompatibility studies.

FDA tentatively concludes, therefore, that the transabdominal amnioscope and accessories should undergo premarket approval to determine whether the probable benefits to health from use of the device for its intended uses and conditions of use outweigh any probable risks to the fetus and the mother.

Any PMA for the device is to contain the information required by section 515(e)(1)(A) of the act. Such a PMA should also contain a detailed discussion with supporting preclinical and clinical studies respecting the risks identified above and the effectiveness of the device for which premarket approval is sought.

In addition, the PMA should contain all data and information on: (1) The risks known to the applicant that have not been identified in this document, (2) the effectiveness of the specific transabdominal amnioscope and its accessories that is the subject of the application, and (3) summaries of all existing preclinical and clinical data from investigations on the safety and effectiveness of the device for which premarket approval is sought.

Applicants should submit any PMA in accordance with FDA's "Guideline for the Arrangement and Content of a PMA Application." (The guideline is available upon request from Raju G. Kammula, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.)

### Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(iv) of the act and § 860.132 of FDA's regulations governing classification of devices (21 CFR 860.132) to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. The legal standard governing reclassification under section 513(e) of the act and § 860.123 is discussed in detail in the preambles to FDA's proposed rules to reclassify daily wear spherical contact lenses consisting of rigid gas permeable plastic materials and daily wear optically spherical (soft) contact lenses from class III into class I (47 FR 53402, 53411; November 26, 1982).

A request for a change in the classification of the transabdominal amnioscope and accessories is to be in the form of a reclassification petition containing the information required by § 860.123, including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by March 18, 1986.

The agency advises that to assure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the transabdominal amnioscope and accessories is submitted, the agency will, by May 2, 1986, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and §860.130 of the regulations.

### References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.


1. Alter, B. P., "Prenatal Diagnosis of Hemoglobinopathies and Other Hematologic Diseases, " *Journal of Pediatrics*, 95:501–513, 1979.

2. Antsaklis, A. J., "Fetoscopy at First Department of Obstetrics and Gynecology, Athens University," *in* "Fetoscopy," Edited by Rocker, I., and K. M. Laurence, New York, Elsevier/North-Holland, pp. 277–285, 1981.

3. Benzie, R., et al., "Fetoscopy and Fetal Tissue Sampling," *Prenatal Diagnosis* (Special Issue), pp. 29–33, 1980.

4. Elias, S., "Fetoscopy in Prenatal Diagnosis," *Clinics in Perinatology*, 10:357–367, 1983.

5. Elias, S., and N. B. Esterly, "Prenatal Diagnosis of Hereditary Skin Disorders," *Clinical Obstetrics and Gynecology*, 24:1069–1087, 1981.

6. Fairweather, D. V. I., R. H. Ward, and B. Modell, "Obstetric Aspects of Mid-Trimester Fetal Blood Sampling by Needling or Fetoscopy," *British Journal of Obstetrics and Gynecology*, 87:87–99, 1980.

7. Firshein, S. I., et al., "Prenatal Diagnosis of Classic Hemophilia," *New England Journal of Medicine*, 300:937–941, 1979.

8. Hobbins, J.C., and M. J. Mahoney, "In Utero Diagnosis of Hemoglobinopathies. Technic for Obtaining Fetal Blood." *New England Journal of Medicine*, 290:1065–1067, 1974.

9. Mibashan, R. S., et al., "Plasma Assay of Fetal Factors VIIIC and IX for Prenatal Diagnosis of Hemophilia," *Lancet*, i, 1309–1311, 1979.

10. Newburger, P. E., et al., "Prenatal Diagnosis of Chronic Granulomatous Disease," *New England Journal of Medicine*, 300:178–181, 1979.

11. Philip, J., et al., "ABO and Rh Phenotyping of Foetal Blood Obtained by Foetoscopy," *Clinical Genetics*, 14:324–329, 1978.

12. Rauskolb, R., "Fetoscopy in Germany," *in* "Fetoscopy," Edited by Rocker, I., and K. M. Laurence, New York, Elsevier/North-Holland, pp. 287–298, 1981.

13. Rauskolb, R., "Fetoscopy," *Journal of Perinatal Medicine*, 11:223–231, 1983.

14. Rocker, I., and K. M. Laurence, "An Assessment of Fetoscopy," *in* "Fetoscopy," Edited by Rocker, I., and K. M. Laurence, New York, Elsevier/North-Holland, pp. 301–309, 1981.

15. Rodeck, C. H., and S. Campbell, "Early Prenatal Diagnosis of Neural-Tube Defects by Ultrasound-Guided Fetoscopy," *Lancet*, i, 1128–1129, 1978.

16. Rodeck, C. H., and K. H. Nicolaides, "Fetoscopy and Fetal Tissue Sampling," *British Medical Bulletin*, 39:332–337, 1983.
17. Rodeck, C. H., "Fetoscopy at King's College Hospital London," *in* "Fetoscopy," Edited by Rocker, I., and K. M. Laurence, New York, Elsevier/North-Holland, pp. 233–259, 1981.
18. Rodeck, C. H., "Prenatal Diagnosis by Fetoscopy and Chorion Biopsy," *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 24:86–90, 1984.
19. Special Report: "The Status of Fetoscopy and Fetal Tissue Sampling," Fourth Annual Meeting of the International Fetoscopy Group, San Francisco, 1982, *Prenatal Diagnosis*, 4:79–81, 1984.
20. Toftager-Larsen, K., and R. J. Benzie, "Fetoscopy in Prenatal Diagnosis of the Majewski and the Saldino-Noonan Types of the Short Rib-Polydactyly Syndromes," *Clinical Genetics*, 26:56–60, 1984.
21. Tolarova, M., and A. Zwinger, "The Use of Fetoscopy by Inborn Morphological Anomalies," *Acta Chir. Plasticae*, 23: 139–151, 1981.
22. Walters, W. A. W., et al., "Antenatal Intrauterine Diagnosis of Fetal Thalassaemia," *The Medical Journal of Australia*, 140:260–263, 1984.
23. Ward, R. H. T., and B. Modell, "The Mid-Trimester of Pregnancy in Relation to Fetoscopy and to Fetal Blood Sampling," *in* "Fetoscopy," Edited by Rocker, I., and K. M. Laurence, New York, Elsevier/North-Holland, pp. 3–31, 1981.

### Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### Economic Impact

FDA has examined the economic consequences of this proposed rule in accordance with the criteria in section 1(b) of Executive Order 12291 and found that the proposal would not be a major rule as specified in the Order. The agency believes that only four or five small firms will be affected by this proposed rule. Therefore, the agency certifies under the Regulatory Flexibility Act (Pub. L. 96–354) that the proposed rule would not have a significant economic impact on a substantial number of small entities. An assessment of the economic impact of any final rule based on this proposal has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

### Comments

Interested persons may, on or before May 2, 1986, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before March 18, 1986, submit to the Dockets Management Branch a written request to change the classification of the transabdominal amnioscope and accessories. Two copies of any requests are to be submitted, except that individuals may submit one copy. Comments or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 884 be amended as follows:

## PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR Part 884 is revised to read as follows:

**Authority:** Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)); 21 CFR 5.10; §§ 884.1600(c), 884.5360(d), and 884.5380(c) also are issued under secs. 501, 515, and 520(g), 52 Stat. 1049–1050 as amended, 90 Stat. 552–559, 569–571 (21 U.S.C. 351, 360e, 360j(g)).

2. In Part 884, § 884.1600 is amended by adding new paragraph (c), to read as follows:

**§ 884.1600 Transabdominal amnioscope (fetoscope) and accessories.**

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (a date 90 days after date of promulgation of a final rule) for any transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976, or that has on or before (a date 90 days after date of promulgation of a final rule) been found to be substantially equivalent to a transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976. Any other transabdominal amnioscope (fetoscope) and accessories shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: February 6, 1986.

**Joseph P. Hile,**

*Associate Commissioner for Regulatory Affairs.*

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Federal Register

Monday
March 3, 1986

Part VI

# Department of the Interior

**Bureau of Land Management**

**43 CFR Part 4700**

**Revision of Existing Regulations on Protection, Management, and Control of Wild Free-Roaming Horses and Burros; Final Rule**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Land Management**

**43 CFR Part 4700**

**[Circular No. 2577]**

## Revision of Existing Regulations on Protection, Management, and Control of Wild Free-Roaming Horses and Burros

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Final rulemaking.

**SUMMARY:** This final rulemaking revises the provisions on wild free-roaming horses and burros in Part 4700 to reduce the regulatory burden on the public, to clarify the management procedures of the Bureau of Land Management as they affect the public, to remove unnecessary provisions, and to improve the organization of the regulations.

**EFFECTIVE DATE:** April 2, 1986.

**ADDRESS:** Inquiries or suggestions should be sent to: Director (250), Bureau of Land Management, Room 901, Premier Building, Department of the Interior, Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** John S. Boyles (202) 653–9215.

**SUPPLEMENTARY INFORMATION:** A proposed rulemaking to revise the existing regulations on the protection, managment, and control of wild free-roaming horses and burros on public lands was published in the **Federal Register** on December 18, 1984 (49 FR 49252). Comments were invited for a period of 60 days ending February 19, 1985, during which period a total of 19 comments were received, with 10 from associations, 6 from Federal agency offices, 2 from State governments, and 1 from a Member of Congress. All of the comments have been given careful consideration during the decisionmaking process on this final rulemaking.

The comments contained discussions of specific sections of the proposed rulemaking and in many instances recommended changes, some of which have been adopted in this final rulemaking. This preamble will discuss only those sections that were the subject of specific comments or were changed.

*Section 4700.0–2 Objectives.*

One comment suggested that the objectives should be amended to conform more closely to the statutory objectives stated in the Act of December 15, 1971, as amended (16 U.S.C. 1331–1340) (the Act). Based on this comment, the section has been amended to incorporate the statutory requirement that wild horses and burros be managed "as an integral part of the natural system of the public lands" under the principle of multiple use.

*Section 4700.0–5 Definitions.*

Several comments addressed the proposed definitions of the terms "appropriate management level" and "excess animals." Most of the comments criticized the proposed definitions of the terms as being inconsistent with the statutory definitions and intent, and urged that the statutory language be used. In response to these comments, the definitions of both terms have been removed from the final rulemaking. The language of the statute will govern management.

One comment questioned whether the definition of "authorized officer" allows for appeals by the public to higher authority. The definition merely defines who is to carry out the provisions of this rulemaking, and has no bearing on appeals under the Administrative Procedure Act or 43 CFR Part 4 of any decision made under these regulations. The definition is not changed in the final rulemaking.

Two comments addressed the definitions for "band" and "herd", urging that the former be removed and that the latter be conformed to the language in the Act. In response to these comments, the definitions of both terms have been removed from the rulemaking. "Herd" is defined in the Act. "Band" is not used in the text of the final rulemaking, and thus does not require definition.

Several comments addressed the definition of "commercial exploitation," urging that it be expanded to include slaughtering and processing the remains of horses and burros, and not be limited to using the wild characteristics of the animals for financial gain. Slaughtering a wild horse or burro is prohibited by § 4770.1(c) of this relemaking, and selling a wild horse or burro or its remains is prohibited by § 4770.1(d). Processing of the remains of a wild horse or burro is addressed in § 4730.2 , which prohibits receiving compensation for remains, but allows disposal of remains through rendering. The definition is retained unchanged.

Several comments objected to the proposed definition of "humane treatment," which required that handling be consistent with "standard animal husbandry practices." Because no specific group of husbandry practices can be presented as a "standard," the word has been replaced in the final rulemaking with the phrase "accepted by the veterinary community." Accepted animal husbandry practices are those outlined in textbooks on the subject. The BLM has relied primarily on the following:

1. Bradley, Melvin. *Horses: A Practical and Scientific Approach*. New York: McGraw-Hill, Inc., 1981.

2. Ensminger, M.E. *Horses and Horsemanship*, 5th ed. Danville, Illinois: The Interstate Printers and Publishers, Inc., 1977.

In addition, the adjectives "kind" and "merciful" have been removed because they are redundant, given the requirement that handling not cause unnecessary stress or suffering.

Another comment stated that "stress," referred to in the definition, is undefined. In this and all other cases where common words or expressions are used, the ordinary dictionary definition is intended to be applied.

Several comments addressed the definition of "inhumane treatment." Some stated a preference for the definition in the existing regulations; others stated that requiring the treatment to be intentional is too restrictive, and that it should be defined to include inflicting pain and suffering. The word "death" has been replaced in the definition in the final rulemaking with "undue suffering", in response to one of the comments, and to allow the authorized officer to destroy animals in appropriate circumstances. The definition has also been expanded to include negligent as well as intentional behavior, and the word "standard" is replaced for the reasons stated above. However, the definition in the existing regulations is not retained because it may be too restrictive, in that it includes a specific list of proscribed acts or omissions without stating clearly that other acts or omissions may constitute inhumane treatment.

One comment suggested that the definition of "old wild horse or burro" should be amended to make it clear that, to be subject to destruction as an act of mercy because of physical deterioration, the animal's deterioration must have rendered it unable to fend for itself. This suggestion has been adopted in the final rulemaking.

One comment stated that the definition of "wild horses and burros" should be amended to include their progeny. This change has not been adopted in the final rulemaking because it would include animals born after their mothers have been placed under a Private Maintenance and Care Agreement. Such animals have never been "unbranded or unclaimed horses and burros on public lands of the United States," the statutory definition of wild horses and burros. The final rulemaking

does address progeny born while the mothers are on public land or at adoption centers. In response to a comment, the definition has been amended to assure that the term includes the characteristic "free-roaming".

One comment suggested including in the rulemaking a definition for "herd area." This suggestion has been adopted in the final rulemaking. Two comments urged that a definition of "malicious harassment" be included. This request has not been adopted in the final rulemaking. Instead, the prohibition in § 4770.1(a) has been amended to prohibit negligent as well as malicious injury or harassment. The terms negligence and malice are both well-defined in the law.

*Section 4700.0–6 Policy.*

Several comments addressed paragraph (a) of this section, urging that the policy should emphasize that wild horses and burros should be managed as one of the multiple uses of the public lands, not as a dominant use limited only by the capacity of the habitat. Other comments urged that more than just museum-exhibit populations should be maintained on the public lands. Paragraph (a) of § 4700.0–6 has been amended in the final rulemaking to accommodate both suggestions, that is, to require that populations be self-sustaining and that populations of horses and burros be kept in balance with other uses as well as the productive capacity of the habitat.

Several comments addressed paragraph (b) of this section, urging that the language on forage allocation in the existing regulations (43 CFR 4700.0–6(c)) be retained. Other comments stated that the word "comparably" is vague and should be replaced by "equivalent" in describing how wild horses and burros will be considered in relation to other resources in formulating land use plans. Specific provision for forage allocation is not necessary because the policy is clearly stated that wild horse and burro management will maintain self-sustaining populations. This cannot be done without adequate forage. The word "comparably" is used in the existing regulations to require all resource values to be considered in proportion to their presence on the land, competition with other resources, and the interest of the public in them. Assigning equal or equivalent weight to all resources, as some comments suggested, would not allow varying circumstances to be treated appropriately. The paragraph is not changed in the final rulemaking.

Two comments addressed paragraph (c) of this section, urging that it be policy to manage wild horses and burros at the minimum feasible level, and expressing concern that maintaining free-roaming behavior of the animals may be inconsistent with multiple use of the public lands. Failure to maintain the free-roaming nature of the animals would be contrary to the policy established by the Act. The requirement that management shall be at the minimum level to attain planning objectives is contained in § 4710.4. It is not necessary to amend this provision.

One comment urged that paragraph (d) of this section be amended to preclude cooperative arrangements for the management of wild horses and burros. The Act specifically authorizes the Secretary of the Interior to enter into cooperative agreements with State and local governments and with individual landowners to attain management objectives. The paragraph is retained in the final rulemaking. It should be understood that § 4710.7 retains the statutory provisions for individuals to maintain wild horses and burros on their private land.

Although there were no comments on paragaph (e), it has been amended by removing the word "nationwide" in reference to adoption centers, to avoid misleading the public into expecting to find adoptable animals in every community around the country.

In response to several comments, and to make it consistent with § 4750.4–2(b), paragraph (f) has been amended to state that adoption fees will "normally" be required.

One comment asked for a policy declaration on removal of animals from private land. Such a declaration is unnecessary because the procedure is clearly stated in § 4720.2–1. Another comment asked that management guidelines be included in the policy statement. Such guidelines are more appropriately stated in manuals for the use of field personnel of the Bureau. Neither suggestion has been adopted in the final rulemaking.

*Section 4710.1 Land use planning.*

Several comments addressed this section. One expressed general support, another asked for language requiring that management activities comply with law and Congressional intent, and a third urged that management activities be included in approved land use plans. In response to the second comment, management activities shall be in accordance with the law regardless of any criteria in regulations. In response to the third, the paragraph has been amended by substituting the words "in accordance" for "compatible" in describing the relationship of management actions to land use plans. Management activities, including the development of herd management area plans, must not only be compatible with the land use plan but must also reflect specific guidance derivable from the land use plan on the subjects of resource allocation, relationships between wild horses and burros and other recognized uses, and critical resource use levels that would require modification of the plan's multiple-use prescriptions.

*Section 4710.2 Inventory and monitoring.*

Several comments urged that the authorized officer be required to address the numbers of horses and burros that existed in herd areas in 1971 as a basis for further management. This suggestion is not adopted in the final rulemaking. There is no indication in the Act or its legislative history that herds should be managed at their 1971 size or any other specific level. Furthermore, although estimates of 1971 population levels have been made, they are at best conjectural and highly unreliable. It is more appropriate to allow the authorized officer the flexibility to determine appropriate management levels based on analysis of competing land uses, forage availability, and public concern.

Another comment urged that the authorized officer be required to monitor herd and habitat characteristics regardless of whether herd management areas are established. This suggestion has not been adopted in the final rulemaking, because this type of information is useful only when herds are to be managed in the long term. This provision has been amended to delete the list of items to be inventoried and monitored on herd management areas, because these will vary depending on the objectives in the herd management area plan.

*Section 4710.3–1 Herd management areas.*

Several comments addressed this section, expressing concern that it could be interpreted to direct every District Manager of the Bureau of Land Management to establish herd management areas. This provision has been amended to alleviate this concern and to clarify that herd management areas shall be established only where herds existed in 1971. One comment suggested that the effect on nearby private land of management for wild horses and burros should be taken into account in delineating herd management areas. This suggestion has been adopted in the final rulemaking.

*Section 4710.3–2 Wild horse and burro ranges.*

Several comments objected to this section as implying that numerous wild horse and burro ranges will be

established on public lands. Such ranges are specifically provided for by law (16 U.S.C. 1333(a)), and will be established only upon completion of the appropriate planning process, including public participation. The section has been retained, with editorial changes, in the final rulemaking.

*Section 4710.4 Constraints on management.*

Several comments addressed this section, pointing out that limiting wild horses and burros to their 1971 "yearlong" habitat could effectively eliminate most of their actual habitat from management as herd areas, due to their seasonal use of some areas. The section has been amended to remove the reference to yearlong habitat. In this connection, a definition has been added for "herd area" in § 4700.0–5. Another change has been incorporated to make it clear that management will not be restricted to herd areas, but will rather be undertaken with the objective of limiting animal distribution to herd areas by controlling herd size to prevent habitat from being overpopulated.

*Section 4710.5 Closure to livestock grazing.*

Numerous comments addressed paragraph (a) of this section, either opposing it as inconsistent with multiple use management, or urging that it be amended to provide additional protection for wild horses and burros. Actions under this section are discretionary with the authorized officer and subject to public consultation. The provision is necessary to allow the authorized officer to meet the needs of all users of the public lands, including wild horses and burros, and is retained unamended in the final rulemaking.

Several comments asked that paragraph (b) of this section be amended to allow camp horses or riding stock to graze on public lands inhabited by wild horses and burros. The paragraph has been amended to make it clear that herd areas are closed only to grazing under permit or lease by domestic horses and burros, and not to pack or camp horses. In addition, for the latter it is the normal practice that outfitters carry fodder for their animals with them, or limit their grazing by tying or hobbling them, so interference by these animals with or consumption of forage needed by wild horses and burros is minimal.

As a result of concerns expressed in numerous comments, paragraph (c) of this section has been rewritten in the final rulemaking to clarify the limits on the authority of the authorized officer. Sufficient authorities for this provision are found in the Taylor Grazing Act and the Federal Land Policy and Management Act, as well as the Wild Free-Roaming Horse and Burro Act. Any notice of closure will be subject to the normal administrative appeal process.

*Section 4710.6 Removal of unauthorized livestock in or near areas occupied by wild horses or burros.*

In response to public comment, this section has been amended to make it clear that any conditions established for the removal of unauthorized livestock would apply only to removal from public lands.

*Section 4710.7 Maintenance of wild horses and burros on privately controlled lands.*

This section has been amended to remove the requirement that private maintenance occur only on unfenced land, because that requirement is not supported by law. Landowners may voluntarily provide for and maintain wild horses and burros that freely move onto their land, whether it is fenced or not.

*Section 4720.1 Removal.*

One comment discussed the term "current information" in this section, and suggested that detailed language in the statute at 16 U.S.C. 1333(b)(2) be included in the regulation. The authorized officer is equally bound by the statute and the regulations, and there is no need to repeat the requirements of the law in the regulations. The comment is not adopted in the final rulemaking.

An editorial change has been made in § 4720.1(b), adding the word "humanely" to meet the requirements of law.

Three comments addressed paragraph (c) of this section, 2 of them urging that it be removed from the rulemaking, and 1 asking that a time limit be set for holding captured animals. Section 1333(b)(2)(C) of the Act requires the humane destruction of excess wild horses and burros. Even if the section were removed from the rulemaking, the responsibility to carry out the law would remain. Retaining the paragraph in the rulemaking makes it clear that the Secretary may impose standards for humane destruction of excess animals. Setting a time limit on holding captured animals would deprive the authorized officer of flexibility needed to meet various circumstances, such as temporary lulls in adoption demand.

*Section 4720.2–1 Removal of strayed animals from private lands.*

Several comments addressed this section, stating that the information requested from private landowners seeking removal of strayed animals from their land was too burdensome and should be supplied only in the discretion of the landowner. However, it would be impossible for the authorized officer to be responsive to a request for removal of strayed animals without specific information about the number of animals involved, their location and that of the private lands, and the dates the animals were observed. Requiring this information would enable the authorized officer to determine the appropriate agency action and to assign to each individual request its appropriate priority. Therefore, the final rulemaking makes the content of such requests mandatory by replacing the word "should" with "shall." Other comments urged that the regulation require immediate or priority removal of strayed animals. The comments are not adopted in the final rulemaking, because circumstances may make such action impossible. Requiring that removal be accomplished as soon as practicable commits the Bureau to expeditious removal of strayed animals.

*Section 4720.2–2 Removal of excess animals from private lands.*

One comment stated that the authorized officer should not be required to obtain written permission from the owners of unimproved private lands intermingled with public lands in herd areas when removing excess animals. This comment has been adopted in the final rulemaking by removing the phrase "or using". A sentence has been added to make it clear that flying aircraft over a parcel of land does not constitute entry.

*Section 4730.1 Destruction.*

Several comments addressed this section, observing both the Congressional intent that destruction be a tool for managing wild horses and burros, and the legislatively drawn distinction between destruction of excess animals and destruction of old, sick, and lame animals as an act of mercy. The section has been rewritten in the final rulemaking to conform to the statute in these respects.

*Section 4730.2 Disposal of remains.*

Several comments addressed this section, some urging that it prohibit processing of remains, and others that some provision be made for compensating individuals for disposal of remains. Neither suggestion has been adopted in the final rulemaking. To provide consistency with the Act, and to remove the ambiguity between the words "carcasses" and "remains", the former has been replaced with the latter wherever it appeared. Processing remains is the most appropriate way of disposing of them and complies with the law so long as neither the Bureau nor any individual receives compensation for conveying the remains. Although no compensation can be received for

transfer of the remains, once the remains have been sanitarily rendered in accordance with normal local or State standards, the renderer may sell the end products, which are no longer considered remains as used in the Act.

In response to one comment, the section has been amended to make it clear that the Bureau is not required to dispose of remains of animals that die on the open public range.

*Section 4740.1 Use of motor vehicles or aircraft.*

This section has been amended to reflect numerous comments stating generally that management activities should be conducted in a humane manner, and to clarify that a public hearing shall be held before using helicopters or motor vehicles in the management of wild horses and burros.

*Section 4740.2 Standards for vehicles used for transport of wild horses and burros.*

Two comments urged that this section be amended to provide specific standards for head room in horse trailers and to require that food given to animals in transit be compatible with what they are accustomed to. Such specificity is unnecessary in these regulations. Bureau personnel are trained to judge whether trailers are suitable for transporting individual animals, and allowing feed rations to change while remaining adequate may help adopted animals adjust to their new environments.

*Section 4750.2–1 Health and identification requirements.*

One comment suggested that verification of an animal's soundness and health, required in paragraph (a) of this section, should be obtained from a licensed veterinarian. This recommendation would eliminate the possibility of obtaining a verification from other qualified individuals. Another comment recommended that the provision for tests, immunizations, and worming be removed from the rulemaking because they are not required by Federal law. These tests may not be required by Federal law, but are required by the laws of many of the public land States. Neither recommendation has been adopted in the final rulemaking.

One comment sought the removal of the provision in paragraph (c) for freeze-marking unweaned foals, because of possible stress on the young animals and because of doubt as to their status as free-roaming if born after their dams have been rounded up. This comment has not been adopted in the final rulemaking. Foals born in captivity but before their dams are adopted into private maintenance are considerd free-roaming for purposes of these regulations. Also, while freeze-marking may involve some stress, it is the most humane and cost-efficient way of providing the necessary identification of these animals.

*Section 4750.3–1 Application for private maintenance of wild horses and burros.*

Several comments urged that the provision for a nonrefundable filing fee to accompany the application be removed from the regulations, on the grounds that imposing a fee would tend to discourage adoptions. The recommendation is adopted in the final rulemaking.

*Section 4750.3–2 Qualification standards for private maintenance.*

One comment address paragraph (a)(1) of this section, asking that legal age be determined by where an applicant is a citizen or permanent resident. To avoid the confusion inherent in making this kind of determination, the provision has been amended in the final rulemaking to require only that the applicant be at least 18 years old.

One comment requested that the rulemaking state the minimum acceptable standards for facilities for animals in private maintenance. Paragraph (a)(3) has been rewritten to state those standards.

*Section 4750.3–3 Supporting information and certification for private maintenance of more than 4 wild horses and burros.*

The opening paragraph of § 4750.3–3(a) has been rewritten for purposes of clarification and stricter compliance with the judicial settlement in *American Horse Protection Association, Inc., et al v. Watt, et al* (the AHPA settlement). The amendment makes it clear that the facilities must be physically inspected by a person determined by the authorized officer to be qualified.

Paragraph (a)(1) of this section has been amended to cross-refer to the standards contained in the previous section, in order to make clear the responsibilities of those seeking to adopt more than 4 horses or burros. Paragraph (b) has been rewritten to be more consistent with the AHPA settlement. In the final rulemaking this paragraph makes it clear that the required information is to be provided by holders of powers of attorney to adopt animals on behalf of members of a group.

*Section 4750.4–1 Private Maintenance and Care Agreement.*

Paragraphs (b), (c), and (d) of this section have been removed in the final rulemaking, and the remaining paragraphs redesignated, to eliminate duplication between the provisions stated in the agreement required by this section and the acts prohibited in § 4770.1.

One comment suggested that paragraph (e) of the proposed rulemaking be amended to prohibit long-term or indefinite as well as permanent transfers of adopted animals without prior approval by the authorized officer. This comment has been adopted in the final rulemaking in paragraph (b) by imposing a 30-day limit on transfers without such prior approval.

One comment suggested that adopters be given a definite time within which an animal must be made available for inspection after written request by the authorized office under paragraph (f). This recommendation has been adopted in the final rulemaking by imposing a 7–day deadline.

Two comments suggested that paragraph (g) of the proposed rulemaking ((d) in this final rulemaking) be amended to require a veterinarian's certificate in all cases of the death of an adopted animal. This suggestion has not been adopted in the final rulemaking, but it remains within the discretion of the authorized officer to require such a certificate.

One comment requested more specificity in paragraph (h) of this section in the proposed rulemaking. In response, the paragraph has been amended to make it clear that it is the adopter's financial responsibility to care for animals covered by the Private Maintenance and Care Agreement. New paragraphs have been added to clarify that the adopter is responsible for managing adopted animals, for damages cause by them, for rounding up strays, and for disposal of dead animals. In response to a comment, a requirement has been added that the adopter notify the authorized office of any change of address.

*Section 4750.4–2 Adoption fee.*

Paragraph (a) of this section has been amended in the final rulemaking to conform to the amendment of § 4750.3–1, which removed the application fee. An editorial change has also been made to make it clear that only unweaned foals are not subject to the adoption fee.

*Section 4750.4–3 Request to terminate Private Maintenance and Care Agreement.*

In response to a comment, this section has been amended to clarify that adopted animals may be transferred directly to a new adopter, with the approval of the authorized officer, and that the officer need not take physical possession of animals involved in such transfers.

*Section 4750.4–4 Replacement animals.*

One comment from a Bureau field office suggested shortening from 60 to 10 days the period within which an adopter can obtain an animal to replace one that has died or had to be destroyed due to a condition that existed at the time of adoption. This suggestion was not adopted. Instead, because some conditions that may cause death after a 60-day period may have existed at the time of adoption, this section has been amended to extend the time to 6 months.

*Section 4750.5 Application for title to wild horses and burros.*

Several comments objected to the provision in paragraph (a) of this section allowing adopters to acquire title to more than 4 animals in one year as not being supported by section 1333(c) of the Act. The provision has been removed in the final rulemaking.

One comment requested that paragraph (b) of this section be amended to state in some detail the required contents of the veterinarian's statement to be supplied by the applicant for title. In response to this comment, the word "humane" has been inserted in front of "treatment," so that the required certification will incorporate the elements listed in the definition (§ 4700.0–5(g)) of "human treatment," i.e., handling compatible with standard animal husbandry practices.

Another change has been made in the final rulemaking affecting title application. Application for title has been incorporated in the adoption process so that an adopter applies for title to an animal automatically at the time the Private Maintenance and Care Agreement is signed. The final sentence of the paragraph has been removed as redundant.

*Section 4760 Compliance with the Private Maintenance and Care Agreement.*

A new paragraph (b) has been added to this section to conform it to the terms of the settlement in *American Horse Protection Association v. Watt.* Paragraph (b) requires the authorized officer to verify compliance with the Private Maintenance and Care Agreement when one adopter has acquired 25 or more animals, or 25 or more are maintained in one place.

One comment pointed out that paragraph (b) of this section in the proposed rulemaking (relettered (c) in the final rulemaking), when read in conjunction with § 4750.4–1(f), requires the authorized officer investigating a complaint about the care, treatment, or use of an adopted animal to notify the adopter in writing before inspecting the animal or the facilities where it is maintained. This is a correct statement of the requirement, which is not changed in the final rulemaking. However, the authorized officer may enlist the assistance of Federal or local law enforcement authorities, who may with proper cause obtain a search warrant and investigate without such warning.

*Section 4770.1 Prohibited acts.*

One comment stated that paragraph (a) of this section demonstrates the need for a definition of "malicious harassment," and another stated that the prohibition in this paragraph would be very hard to enforce because of the difficulty of proving malicious intent. The paragraph has been amended to prohibit negligent as well as malicious injury of a wild horse or burro.

The separate prohibition against using a wild horse or burro for bucking stock has been removed from the final rulemaking. Any use considered to be inhumane is already prohibited in § 4770.1(e), and use that takes advantage of an animal's characteristic of wildness is prohibited in § 4770.1(e).

A paragraph has been added to this section prohibiting the violation of orders, terms, or conditions established by the authorized officer. Other changes of an editorial nature have been made.

*Section 4770.2 Civil penalties*

In response to several comments that this section singled out holders of grazing permits for discriminatory treatment, paragraph (a) of this section has been amended to apply to all permittees or lessees on the pubic lands.

The principal author of this final rulemaking is John S. Boyles, Division of Wild Horses and Burros, assisted by the staff of the Office of Legislation and Regulatory Management, Bureau of Land Management.

It is hereby determined that this rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)) is required.

The Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). A limited number of veterinarians, cooperative extension agents, and humane officials may be insignificantly affected by the rulemaking. The certification required for adopters to receive title is needed on a nonrecurring basis. The changes allow adopters discretion to choose the official from whom they obtain a certification, resulting in some cost savings. Adopters are required to pay a fee to obtain the animals and to provide information to show their ability to provide humane transport, facilities, and care for the animals. An insignificant number of individuals may be deterred from participating because of the fee or qualification standards for humane care.

Information collection requirements for administering these regulations have been approved by the Office of Management and Budget and assigned clearance number 1004–0042.

**List of Subjects in 43 CFR Part 4700**

Advisory committees, Aircraft, Intergovernmental relations, Penalties, Public lands, Range management, Wild horses and burros, Wildlife.

Under the provisions of the Act of September 8, 1959 (18 U.S.C. 47), the Act of December 15, 1971, as amended (16 U.S.C. 1331–1340), the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.), and the Act of June 28, 1934, as amended (43 U.S.C. 315), Part 4700, Subchapter D, Chapter II, Title 43 of the Code of Federal Regulations is revised to read as set forth below.

Dated: February 7, 1986.

**J. Steven Griles,**

*Assistant Secretary of the Interior.*

**GROUP 4700—WILD FREE-ROAMING HORSE AND BURRO MANAGEMENT**

Note.—The information collection requirements contained in Group 4700 have been approved by the Office of Management and Budget and assigned clearance number 1004–0042. The information is being collected to permit the authorized officer to remove wild horses and burros from private land and to determine whether an application for adoption of and title to wild horses or burros should be granted. Responses are required to obtain benefits.

## PART 4700—PROTECTION, MANAGEMENT, AND CONTROL OF WILD FREE-ROAMING HORSES AND BURROS

**Subpart 4700—General**

Sec.



**Subpart 4710—Management Considerations**

Sec.



**Authority:** Act of Dec. 15, 1971, as amended (16 U.S.C. 1331–1340). Act of Oct. 21, 1976 (43 U.S.C. 1701 et seq.). Act of Sept. 8, 1959 (18 U.S.C. 47). Act of June 28, 1934 (43 U.S.C. 315).

## Subpart 4700—General

### § 4700.0–1 Purpose.

The purpose of these regulations is to implement the laws relating to the protection, management, and control of wild horses and burros under the administration of the Bureau of Land Management.

### § 4700.0–2 Objectives.

The objectives of these regulations are management of wild horses and burros as an integral part of the natural system of the public lands under the principle of multiple use; protection of wild horses and burros from unauthorized capture, branding, harassment or death; and humane care and treatment of wild horses and burros.

### § 4700.0–3 Authority.

The Act of September 8, 1959 (18 U.S.C. 47); the Act of December 15, 1971, as amended (16 U.S.C. 1331–1340); the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1711, 1712, and 1734); the Act of June 28, 1934, as amended (43 U.S.C. 315); and the National Environmental Policy Act of 1969 (42 U.S.C. 4321, 4331–4335, and 4341–4347).

### § 4700.0–5 Definitions.

As used in this part, the term:

(a) "Act" means the Act of December 15, 1971, as amended (16 U.S.C. 1331–1340), commonly referred to as the Wild Free-Roaming Horse and Burro Act.

(b) "Authorized officer" means any employee of the Bureau of Land Management to whom has been delegated the authority to perform the duties described herein.

(c) "Commercial exploitation" means using a wild horse or burro because of its characteristics of wildness for direct or indirect financial gain. Characteristics of wildness include the rebellious and feisty nature of such animals and their defiance of man as exhibited in their undomesticated and untamed state. Use as saddle or pack stock and other uses that require domestication of the animal are not commercial exploitation of the animals because of their characteristics of wildness.

(d) "Herd area" means the geographic area identified as having been used by a herd as its habitat in 1971.

(e) "Humane treatment" means handling compatible with animal husbandry practices accepted in the veterinary community, without causing unnecessary stress or suffering to a wild horse or burro.

(f) "Inhumane treatment" means any intentional or negligent action or failure to act that causes stress, injury, or undue suffering to a wild horse or burro and is not compatible with animal husbandry practices accepted in the veterinary community.

(g) "Lame wild horse or burro" means a wild horse or burro with one or more malfunctioning limbs that permanently impair its freedom of movement.

(h) "Old wild horse or burro" means a wild horse or burro characterized because of age by its physical deterioration and inability to fend for itself, suffering, or closeness to death.

(i) "Private maintenance" means the provision of proper care and humane treatment to excess wild horses and burros by qualified individuals under the terms and conditions specified in a Private Maintenance and Care Agreement.

(j) "Public lands" means any lands or interests in lands administered by the Secretary of the Interior through the Bureau of Land Management.

(k) "Sick wild horse or burro" means a wild horse or burro with failing health, infirmity or disease from which there is little chance of recovery.

(l) "Wild horses and burros" means all unbranded and unclaimed horses and burros that use public lands as all or part of their habitat, or that have been removed from these lands by the authorized officer but have not lost their status under section 3 of the Act. Where it appears in this part the term "wild horses and burros" is deemed to include the term "free-roaming".

### § 4700.0–6 Policy.

(a) Wild horses and burros shall be managed as self-sustaining populations of healthy animals in balance with other uses and the productive capacity of their habitat.

(b) Wild horses and burros shall be considered comparably with other resource values in the formulation of land use plans.

(c) Management activities affecting wild horses and burros shall be undertaken with the goal of maintaining free-roaming behavior.

(d) In administering these regulations, the authorized officer shall consult with Federal and State wildlife agencies and all other affected interests, to involve them in planning for and management of wild horses and burros on the public lands.

(e) Healthy excess wild horses and burros for which an adoption demand by qualified individuals exists shall be made available at adoption centers for private maintenance and care.

(f) Fees shall normally be required from qualified individuals adopting

excess wild horses and burros to defray part of the costs of the adoption program.

## Subpart 4710—Management Considerations

### § 4710.1 Land use planning.

Management activities affecting wild horses and burros, including the establishment of herd management areas, shall be in accordance with approved land use plans prepared pursuant to Part 1600 of this title.

### § 4710.2 Inventory and monitoring.

The authorized officer shall maintain a record of the herd areas that existed in 1971, and a current inventory of the numbers of animals and their areas of use. When herd management areas are established, the authorized officer shall also inventory and monitor herd and habitat characteristics.

### § 4710.3 Management areas.

### § 4710.3-1 Herd management areas.

Herd management areas shall be established for the maintenance of wild horse and burro herds. In delineating each herd management area, the authorized officer shall consider the appropriate management level for the herd, the habitat requirements of the animals, the relationships with other uses of the public and adjacent private lands, and the constraints contained in § 4710.4. The authorized officer shall prepare a herd management area plan, which may cover one or more herd management areas.

### § 4710.3-2 Wild horse and burro ranges.

Herd management areas may also be designated as wild horse or burro ranges to be managed principally, but not necessarily exclusively, for wild horse or burro herds.

### § 4710.4 Constraints on management.

Management of wild horses and burros shall be undertaken with the objective of limiting the animals' distribution to herd areas. Management shall be at the minimum level necessary to attain the objectives identified in approved land use plans and herd management area plans.

### § 4710.5 Closure to livestock grazing.

(a) If necessary to provide habitat for wild horses or burros, to implement herd management actions, or to protect wild horses or burros, to implement herd management actions, or to protect wild horses or burros from disease, harassment or injury, the authorized officer may close appropriate areas of the public lands to grazing use by all or a particular kind of livestock.

(b) All public lands inhabited by wild horses or burros shall be closed to grazing under permit or lease by domestic horses and burros.

(c) Closure may be termporary or permanent. After appropriate public consultation, a Notice of Closure shall be issued to affected and interested parties.

### § 4710.6 Removal of unauthorized livestock in or near areas occupied by wild horses or burros.

The authorized officer may establish conditions for the removal of unauthorized livestock from public lands adjacent to or within areas occupied by wild horses or burros to prevent undue harassment of the wild horses or burros. Liability and compensation for damages from unauthorized use shall be determined in accordance with subpart 4150 of this title.

### § 4710.7 Maintenance of wild horses and burros on privately controlled lands

Individuals controlling lands within areas occupied by wild horses and burros may allow wild horses or burros to use these lands. Individuals who maintain wild free-roaming horses and burros on their land shall notify the authorized officer and shall supply a reasonable estimate of the number of such animals so maintained. Individuals shall not remove or entice will horses or burros from the public lands.

## Subpart 4720—Removal

### § 4720.1 Removal of excess animals from public lands.

Upon examination of current information and a determination by the authorized officer that an excess of wild horses or burros exists, the authorized officer shall remove the excess animals immediately in the following order.

(a) Old, sick, or lame animals shall be destroyed in accordance with Subpart 4730 of this title;

(b) Additional excess animals for which an adoption demand by qualified individuals exists shall be humanely captured and made available for private maintenance in accordance with Subpart 4750 of this title; and

(c) Remaining excess animals for which no adoption demand by qualified individuals exists shall be destroyed in accordance with subpart 4730 of this title.

### § 4720.2 Removal of strayed or excess animals from private lands.

### § 4720.2-1 Removal of strayed animals from private lands.

Upon written request from the private landowner to any representative of the Bureau of Land Management, the authorized officer shall remove stray wild horses and burros from private lands as soon as practicable. The private landowner may also submit the written request to a Federal marshal, who shall notify the authorized officer. The request shall indicate the numbers of wild horses or burros, the date(s) the animals were on the land, legal description of the private land, and any special conditions that should be considered in the gathering plan.

### § 4720.2-2 Removal of excess animals from private lands.

If the authorized officer determines that proper management requires the removal of wild horses and burros from areas that include private lands, the authorized officer shall obtain the written consent of the private owner before entering such lands. Flying aircraft over lands does not constitute entry.

## Subpart 4730—Destruction of Wild Horses or Burros and Disposal of Remains

### § 4730.1 Destruction.

Except as an act of mercy, no wild horse or burro shall be destroyed without the authorization of the authorized officer. Old, sick, or lame animals shall be destroyed in the most humane manner possible. Excess animals for which adoption demand does not exist shall be destroyed in the most humane and cost efficient manner possible.

### § 4730.2 Disposal of remains.

Remains of wild horses or burros that die after capture shall be disposed of in accordance with State or local sanitation laws. No compensation of any kind shall be received by any agency or individual disposing of remains. The products of rendering are not considered remains.

## Subpart 4740—Motor Vehicles and Aircraft

### § 4740.1 Use of motor vehicles or aircraft.

(a) Motor vehicles and aircraft may be used by the authorized officer in all phases of the administration of the Act, except that no motor vehicle or aircraft, other than helicopters, shall be used for the purpose of herding or chasing wild horses or burros for capture or

destruction. All such use shall be conducted in a humane manner.

(b) Before using helicopters or motor vehicles in the management of wild horses or burros, the authorized officer shall conduct a public hearing in the area where such use is to be made.

**§ 4740.2 Standards for vehicles used for transport of wild horses and burros.**

(a) Use of motor vehicles for transport of wild horses or burros shall be in accordance with appropriate local, State and Federal laws and regulations applicable to the humane transportation of horses and burros, and shall include, but not be limited to, the following standards:

(1) The interior of enclosures shall be free from protrusion that could injure animals;

(2) Equipment shall be in safe conditions and of sufficient strength to withstand the rigors of transportation;

(3) Enclosures shall have ample head room to allow animals to stand normally;

(4) Enclosures for transporting two or more animals shall have partitions to separate them by age and sex as deemed necessary by the authorized officer;

(5) Floors of enclosures shall be covered with nonskid material;

(6) Enclosures shall be adequately ventilated and offer sufficient protection to animals from inclement weather and temperature extremes; and

(7) Unless otherwise approved by the authorized officer, transportation shall be limited in sequence to a maximum of 24 hours followed by a minimum of 5 hours of on-the-ground rest with adequate feed and water.

(b) The authorized officer shall not load wild horses or burros if he/she determines that the vehicle to be used for transporting the wild horses or burros is not satisfactory for that purpose.

## Subpart 4750—Private Maintenance

**§ 4750.1 Private maintenance.**

The authorized officer shall make available for private maintenance all healthy excess wild horses or burros for which an adoption demand by qualified individuals exists.

**§ 4750.2 Health, identification, and inspection requirements.**

**§ 4750.2-1 Health and identification requirements.**

(a) An individual determined to be qualified by the authorized officer shall verify each excess animal's soundness and good health, determine its age and sex, and administer immunizations, worming compounds, and tests for communicable diseases.

(b) Documentation conforming compliance with State health inspection and immunization requirements for each wild horse or burro shall be provided to each adopter by the authorized officer.

(c) Each animal offered for private maintenance, including orphan and unweaned foals, shall be individually identified by the authorized officer with a permanent freeze mark of alpha numeric symbols on the left side of its neck. The freeze mark identifies the animal as Federal property subject to the provisions of the Act and these regulations by a patented symbol, the animal's year of birth, and its individual identification number. The authorized officer shall record the freeze mark on the documentation of health and immunizations. For purposes of this subpart, a freeze mark applied by the authorized officer is not considered a brand.

**§ 4750.2-2 Brand inspection.**

The authorized officer shall make arrangements on behalf of an adopter for State inspection of brands, where applicable, of each animal to be transported across the State where the adoption center is located. The adopter shall be responsible for obtaining inspections for brands required by other States to or through which the animal may be transported.

**§ 4750.3 Application requirements for private maintenance.**

**§ 4750.3-1 Application for private maintenance of wild horses and burros.**

An individual applying for a wild horse or burro shall file an application with the Bureau of Land Management on a form approved by the Director.

**§ 4750.3-2 Qualification standards for private maintenance.**

(a) To qualify to receive a wild horse or burro for private maintenance, an individual shall:

(1) Be 18 years of age or older;

(2) Have no prior conviction for inhumane treatment of animals or for violation of the Act or these regulations;

(3) Have adequate feed, water, and facilities to provide humane care to the number of animals requested. Facilities shall be in safe condition and of sufficient strength and design to contain the animals. The following standards apply:

(i) A minimum space of 144 square feet shall be provided for each animal maintained, if exercised daily; otherwise, a minimum of 400 square feet shall be provided for each animal;

(ii) Until fence broken, adult horses shall be maintained in an enclosure at least 6 feet high; burros in an enclosure at least 4½ feet high; and horses less than 18 months old in an enclosure at least 5 feet high. Materials shall be protrusion-free and shall not include large-mesh woven or barbed wire;

(iii) Shelter shall be available to mitigate the effects of inclement weather and temperature extremes. The authorized officer may require that the shelter be a structure, which shall be well-drained and adequately ventilated;

(iv) Feed and water shall be adequate to meet the nutritional requirements of the animals, based on their age, physiological condition and level of activity; and

(4) Have obtained no-more than 4 wild horses and burros within the preceding 12-month period, unless specifically authorized in writing by the authorized officer.

(b) The authorized officer shall determine an individual's qualifications based upon information provided in the application form required by § 4750.3-1 of this subpart and Bureau of Land Management records of any previous private maintenance by the individual under the Act.

**§ 4750.3-3 Supporting information and certification for private maintenance of more than 4 wild horses or burros.**

(a) An individual applying for more than 4 wild horses or burros within a 12-month period, or an individual or group of individuals requesting to maintain more than 4 wild horses or burros at a single location shall provide a written report prepared by the authorized officer, or by a local humane official, veterinarian, cooperative extension agent, or similarly qualified person approved by the authorized officer, verifying that the applicant's facilities have been inspected appear adequate to care for the number of animals requested, and satisfy the requirements contained in § 4750.3-2(a).

(1) The report shall include a description of the facilities, including corral sizes, pasture size, and shelter, barn, or stall dimensions, and shall note any discrepancies between the facilities inspected and representations made in the application form.

(2) When an applicant requests 25 or more animals or when 25 or more animals will be maintained at any single location regardless of the number of applicants, the facilities for maintaining the adopted animals shall be inspected by the authorized officer prior to approving the application.

(b) Any individual or group represented by a power of attorney and applying for more than 4 animals shall provide the following:

(1) A summary of the age, sex, and number of wild free-roaming horses or burros requested by species;

(2) Requested adoption date and center location;

(3) If applicable, names, addresses and telephone numbers of all applicants represented by a power of attorney submitted with the request;

(4) A transportation plan that describes the transport vehicle and any rest-stops;

(5) A distribution plan for delivering the animals to their assigned adopters;

(6) Names, addresses, and a concise summary of the experience of the individuals who will handle the adopted animals during transportation and distribution; and

(7) When the adopted animals will be maintained at a single location or where the applicants have been solicited by the holder of their power of attorney, a concise statement outlining the arrangements, including duties and responsibilities of the parties, for maintaining the animals.

**§ 4750.3-4 Approval or disapproval of applications.**

If an application is approved, the authorized officer shall offer the individual an opportunity to select the appropriate number, sex, age and species of animals from those available. If the authorized officer disapproves an application for private maintenance because the applicant lacks adequate facilities or transport, the individual may correct the shortcoming and file a new application.

**§ 4750.4 Private maintenance of wild horses and burros.**

**§ 4750.4-1 Private Maintenance and Care Agreement.**

To obtain a wild horse or burro, a qualified applicant shall execute a Private Maintenance and Care Agreement and agree to abide by its terms and conditions, including but not limited to the following:

(a) Title to wild horses and burros covered by the agreement shall remain in the Federal Government for at least 1 year after the Private Maintenance and Care Agreement is executed and until a Certificate of Title is issued by the authorized officer.

(b) Wild horses and burros covered by the agreement shall not be transferred for more than 30 days to another location or to the care of another individual without the prior approval of the authorized officer;

(c) Wild horses and burros covered by the agreement shall be made available for physical inspection within 7 days of receipt of a written request by the authorized officer;

(d) The authorized officer shall be notified within 7 days of discovery of the death, theft or escape of wild horses and burros covered by the agreement;

(e) Adopters are financially responsible for the proper care and treatment of all wild horses and burros covered by the agreement.

(f) Adopters are responsible, as provided by State law, for any personal injury, property damage, or death caused by animals in their care; for pursing animals that escape or stray; and for costs of recapture.

(g) Adopters shall notify the authorized officer within 30 days of any change in the adopter's address; and

(h) Adopters shall dispose of remains in accordance with applicable sanitation laws.

**§ 4750.4-2 Adoption fee.**

(a) An individual obtaining wild horses and burros shall pay the Bureau of Land Management an adoption fee of $125 per horse and $75 per burro, except that no fee shall be paid for unweaned foals.

(b) The Director may adjust or waive the adoption fee on determining that wild horses or burros in the custody of the Bureau of Land Management are unadoptable when the full adoption fee is required, and that it is in the public interest to adjust or waive the adoption fee stated in paragraph (a) of this section. The adjustment or waiver shall extend only to those persons who are willing to maintain such animals privately, who demonstrate the ability to care for them properly, and who agree to comply with all rules and regulations relating to wild horses and burros.

**§ 4750.4-3 Request to terminate Private Maintenance and Care Agreement.**

An adopter may request to terminate his/her responsibility for an adopted animal by submitting a written relinquishment of the Private Maintenance and Care Agreement for that animal. The authorized officer shall arrange to transfer the animal to another qualified applicant or take possession of the animal at a location specified by the authorized officer within 30 days of receipt of the written request for relinquishment.

**§ 4750.4-4 Replacement animals.**

The authorized officer shall replace an animal, upon request by the adopter, if (a) within 6 months of the execution of the Private Maintenance and Care Agreement the animal dies or is required to be destroyed due to a condition that existed at the time of placement with the adopter; and (b) the adopter provides, within a reasonable time, a statement by a veterinarian certifying that reasonable care and treatment would not have corrected the condition. Transportation of the replacement animal shall be the responsibility of the adopter.

**§ 4750.5 Application for title to wild horses and burros.**

(a) The adopter shall apply for title, using a form designated by the Director, upon signing the Private Maintenance and Care Agreement.

(b) The authorized officer shall issue a Certificate of Title after 12 months, if the adopter has complied with the terms and conditions of the agreement and the authorized officer determines, based either on a field inspection or a statement provided by the adopter from a veterinarian, extension agent, local humane official, or other individual acceptable to the authorized officer, that the animal or animals covered by the Agreement have received proper care and humane treatment.

(c) An adopter may not obtain title to more than 4 animals per 12-month period of private maintenance. Effective the date of issuance of the Certificate of Title, Federal ownership of the wild horse or burro ceases and the animal loses its status as a wild horse or burro and is no longer under the protection of the Act or regulations under this title.

## Subpart 4760—Compliance

**§ 4760.1 Compliance with the Private Maintenance and Care Agreement.**

(a) An adopter shall comply with the terms and conditions of the Private Maintenance and Care Agreement and these regulations. The authorized officer may verify compliance by visits to an adopter, physical inspections of the animals, and inspections of the facilities and conditions in which the animals are being maintained. The authorized officer may authorize a cooperative extension agent, local humane official or similarly qualified individual to verify compliance.

(b) The authorized officer shall verify compliance with the terms of the Private Maintenance and Care Agreement when an adopter has received 25 or more animals or when 25 or more animals are maintained at a single location.

(c) The authorized officer shall conduct an investigation when a complaint concerning the care, treatment, or use of a wild horse or

burro is received by the Bureau of Land Management.

(d) The authorized officer may require, as a condition for continuation of a Private Maintenance and Care Agreement, that an adopter take specific corrective actions if the authorized officer determines that an animal is not receiving proper care or is being maintained in unsatisfactory conditions. The adopter shall be given reasonable time to complete the required corrective actions.

## Subpart 4770—Prohibited Acts, Administrative Remedies, and Penalties

### § 4770.1 Prohibited acts.

The following acts are prohibited:

(a) Maliciously or negligently in juring or harassing a wild horse or burro;

(b) Removing or attempting to remove a wild horse or burro from the public lands without authorization from the authorized officer;

(c) Destroying a wild horse or burro without authorization from the authorized officer except as an act of mercy;

(d) Selling or attempting to sell, directly or indirectly, a wild horse or burro or its remains;

(e) Commercially exploiting a wild horse or burro;

(f) Treating a wild horse or burro inhumanely;

(g) Violating a term or condition of the Private Maintenance and Care Agreement;

(h) Branding a wild horse or burro;

(i) Removing or altering a freeze mark on a wild horse or burro;

(j) Violating an order, term, or condition established by the authorized officer under this part.

### § 4770.2 Civil penalties.

(a) A permittee or lessee who has been convicted of any of the prohibited acts found in § 4770.1 of this title may be subject to suspension or cancellation of the permit or lease.

(b) An adopter's failure to comply with the terms and conditions of the Private Maintenance and Care Agreement may result in the cancellation of the agreement, repossession of wild horses and burros included in the agreement and disapproval of requests by the adopted for additional excess wild horses and burros.

### § 4770.3 Administrative remedies.

Any person who is adversely affected by a decision of the authorized officer in the administration of these regulations may file an appeal in accordance with 43 CFR 4.4 within 30 days of receipt of the written decision.

### § 4770.4 Arrest.

The Director of the Bureau of Land Management may authorize an employee who witnesses a violation of the Act or these regulations to arrest without warrant any person committing the violation, and to take the person immediately for examination or trial before an officer or court of competent jurisdiction. Any employee so authorized shall have power to execute any warrant or other process issued by an officer or court of competent jurisdiction to enforce the provisions of the Act or these regulations.

### § 4770.5 Criminal penalties.

Any person who commits any act prohibited in § 4770.1 of these regulations shall be subject to a fine of not more than $2,000 or imprisonment for not more than 1 year, or both, for each violation. Any person so charged with such violation by the authorized officer may be tried and sentenced by a United States Commissioner or magistrate, designated for that purpose by the court by which he/she was appointed, in the same manner and subject to the same conditions as provided in 18 U.S.C. 3401.

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